Installation Guide

MSii GUI Version	1.0.5009.26063
DB Server Version	1.1.0.0
Reader Comm. Version	1.1.0.3
Firmware Version	mms.2.1
Computer Name	MICROWIN7
Reader UID	
Reader Name	

microSTAR® ii
medical dosimetry system

MicroSTARii® Installation Guide

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MicroSTARii® Installation Guide Overview

This guide contains detailed instructions on how to SETUP the MicroSTARii Medical Dosimetry System, including but not limited to:

Physical and Performance CHARACTERISTICS of the reader
Physical SETUP of the reader and computer
Software CUSTOMIZATION and CONFIGURATION
Reader VERIFICATION
Reader CALIBRATION

NOTE: Pages 3-4 contain an INDEX giving an overview of the steps involved during installation.

NOTE: The MicroSTARii® application software has been pre-installed on the computer included with your system. Should you need to install this software on other computer systems before proceeding with installation, contact Landauer® Customer Service for additional instructions.

1 MicroSTARii® System Installation and Setup

1.1 Reader Physical Characteristics

1.1.1 Reader Front Panel

1.1.1.1 Layout

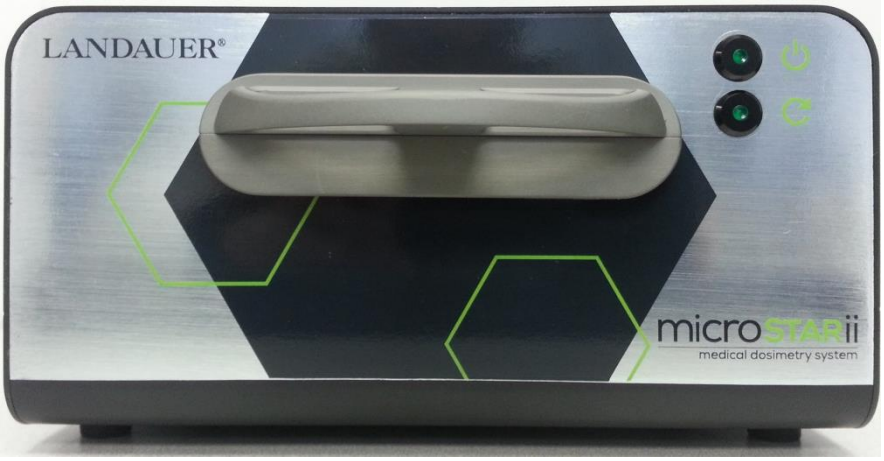


Figure 1: Front of microSTAR® ii reader

1.1.1.2 Features

- A removable drawer for nanoDot™ insertion
- Power LED
- Read LED

1 MicroSTARii® System Installation and Setup (continued)

1.1 Reader Physical Characteristics

1.1.2 Reader Back Panel

1.1.2.1 Layout

Figure 2: Back of microSTAR® ii reader

1.1.2.2 Features

- Socket for screw-on power connector
- Power switch
- USB port
- Serial number label

1 MicroSTARii® System Installation and Setup (continued)

1.1 Reader Physical Characteristics

1.1.3 Placement of a nanoDot™ in the reader drawer

Insert a nanoDot™ into the drawer as pictured below.

The orientation should be such that the 2D barcode is facing up and the label is wrapped around the edge closest to the blue ejector as shown below.

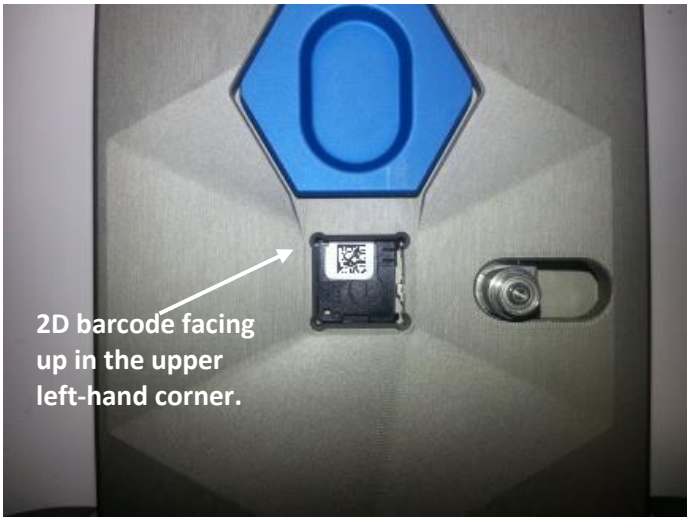


Figure 3: Correct nanoDot™ orientation in reader drawer

WARNING

INSERTING THE NANODOT IN ANY ORIENTATION OTHER THAN THAT PICTURED ABOVE WILL RESULT IN INCORRECT READINGS AND DAMAGE TO THE NANODOT.

ALWAYS INSERT THE NANODOT CAREFULLY AS SHOWN ABOVE AND ENSURE ALL USERS ARE TRAINED IN THE CORRECT PROCEDURE PRIOR TO USE OF THE SYSTEM.

1 MicroSTARii® System Installation and Setup (continued)

1.1 Reader Physical Characteristics

1.1.4 Inserting the drawer into the reader

Position the drawer with the nanoDot™ and ejector facing up as pictured below and slide into the microSTAR® ii reader.

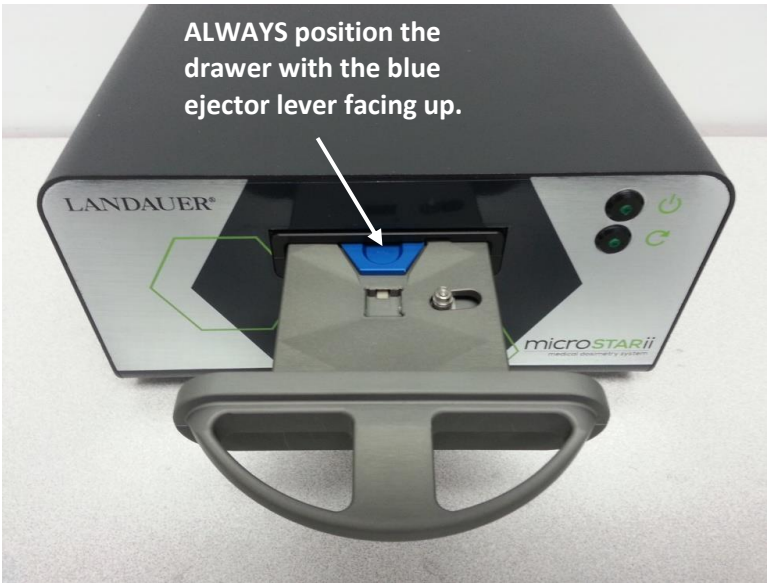


Figure 4: Correct orientation when inserting drawer into microSTAR® ii reader.

WARNING

IMPROPER INSERTION OF THE DRAWER CAN CAUSE SERIOUS DAMAGE TO THE READER!

ALWAYS INSERT THE DRAWER CAREFULLY AS SHOWN ABOVE. NEVER FORCE THE DRAWER INTO THE READER. ENSURE ALL USERS ARE TRAINED IN THE CORRECT INSERTION PROCEDURE PRIOR TO THEIR USE OF THE SYSTEM.

1 MicroSTARii® System Installation and Setup (continued)

1.2 Reader Specifications

1.2.1 Physical Specifications

Dimensions:	Depth: 6.0120 in (152.7mm)
Width:	8.1370 in (206.7mm)
Height:	4.0675 in (103.3mm)
Weight:	5.14 lbs.
Enclosure:	Metal case, powder coated
Connectors:	USB
Power:	6V, 1.0A
Operating Environment:	5°C to 40°C; < 70% RH non-condensing
Storage Environment:	-20°C to 60°C; < 90% RH non-condensing
Use Location	Indoor use only

1.2.2 Performance Specifications

microSTAR® ii		
Metric	**Spec.**	**Notes**
Accuracy:	+/- 5%	*Using screened nanoDots (k=2)*
Precision:	5%	
Repeatability:	≤ 1.0%	Coefficient of Variation; n=10, dose >50+ cGy
Lower Limit of Detection (LLD):		
Strong Beam (Low Dose)	≤ 3 mrad	Lower limits with freshly annealed blanks
Weak Beam (High Dose)	≤ 20 mrad	Lower limits with freshly annealed blanks
Depletion:		
Strong Beam (Low Dose)	≤ 0.60%	Percent depletion per read
Weak Beam (High Dose)	≤ 0.07%	Percent depletion per read
Intrinsic Stability:		
Dark	≤ 20	Counts/second
LED with Photodiode	≤ 3.0%	Coefficient of variation computed across 10 consecutive measurement cycles
LED with PMT	≤ 3.0%	
Light Leakage:	≤ 20	Counts/second

Table 1: MicroSTARii® Performance Specifications

1 MicroSTARii® System Installation and Setup (continued)

1.3 Unpacking and Handling

It is recommended the microSTARii® Medical Dosimetry System comprising the reader, computer and accessories, be unpacked in the lab or office where it will be operated. Unpack the system carefully as small parts, cables and nanoDot dosimeters are included with the shipment. Inspect the box for loose parts before commencing installation. It is strongly recommended that you save the packing material and boxes in the event that a reader needs to be returned for preventive maintenance or service at a later date.

1.4 Inspection for Damage

The microSTARii® Medical Dosimetry System is carefully packed at the factory to minimize the possibility of damage during shipping. However, to ensure there has not been damage in transit, inspect the exterior and contents of the box for signs of damage or mishandling. If there is visible damage to the reader, computer or accessories upon receipt, it is imperative that you inform the shipping company and Landauer Inc., immediately.

1.5 Parts List

The following is a list of parts included with the microSTARii® System:

- MicroSTARii Reader plus accessories which include:
  - Drawer
  - Power supply
  - USB cable
- All-In-One computer plus accessories which include:
  - Keyboard
  - Mouse
  - Power cord
- Barcode scanner
- 1 NIST-traceable 80 kVp or Cs-137 Calibration set
- 1 NIST-traceable 80 kVp or Cs-137 Post-Calibration Verification QC set
- 2 Constancy nanoDots
- Optional: Additional unexposed nanoDot dosimeters (screened or general purpose, if ordered)

IMPORTANT NOTE:

Do not attempt to use the Landauer-supplied NIST-traceable Calibration and QC sets until you have reviewed the usage instructions and recommended installation testing and calibration protocol.

1 MicroSTARii® System Installation and Setup (continued)

1.6 Enviromental Requirements

The microSTARii® Medical Dosimetry System may be operated in most clinical environments having a stable ambient temperature. For best results it is recommended that the system be installed in a dedicated location on a stable surface away from direct sunlight.

IMPORTANT NOTE: It is recommended that dosimeters be stored away from direct sunlight and fluorescent light when not in use,

1.7 Electrical Requirements

Before attempting to install the system, verify the wall socket that will be used is properly polarized and properly grounded. If possible, connect both the reader and the PC into a surge protection power strip and connect the power strip to the wall outlet.

1.8 Physical Setup

Refer to the manufacturer's User manual for PC setup and Operation. After setting up the PC according to the instructions provided by the manufacturer, turn on the PC. When the Windows login window is displayed, use Username: **admin** and Password: **system**, to login to the PC.

To connect the reader to a power source, plug the provided reader power supply adapter plug into an acceptable power outlet. Plug the other end of the power supply connector shown in Figure 5 into the reader and screw down the connector.

To connect the reader to the computer, note that the reader USB cable has two different connectors, one square (USB Type B) and one rectangular (USB Type A). Connect the square end of the USB cable to the reader as depicted in Figure 6. Connect the rectangular end of the USB connector (USB Type A) to any available PC USB port. Note: All USB ports on the PC have been tested for reader compatibility.

To turn on the reader turn the power switch depicted in Figure 7 to the ON position.

Next, connect the barcode scanner to any available USB port on the PC.

When all cables have been correctly connected, the back of the PC should appear as shown in Figure 8.

1 MicroSTARii® System Installation and Setup (continued)

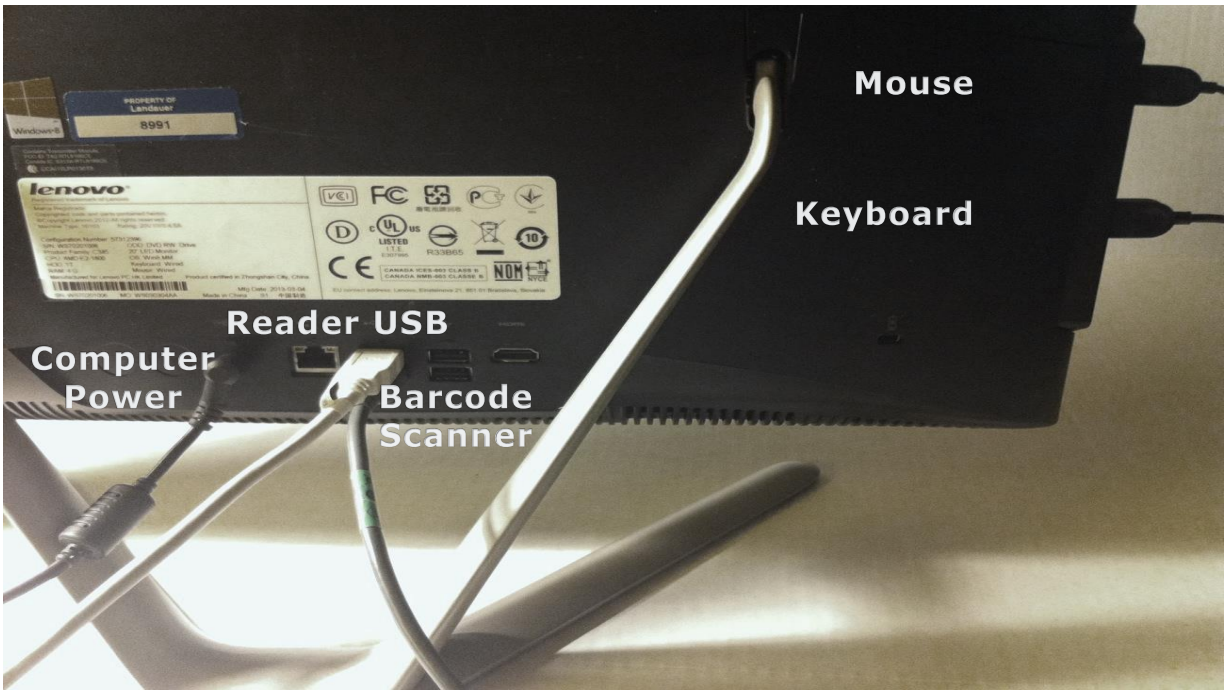
1.8 Physical Setup (continued)

Figure 5: Reader Power Cable

Figure 6: Reader USB Cable

Figure 7: Reader Power Switch

Figure 8: Back of computer USB and power connections



2 MicroSTARii® System Configuration

2.1 Startup microSTARii® Application Software

From the Windows desktop double click the microSTARii® reader application icon to launch the microSTARii Medical Dosimetry System software.

Figure 9: MicroSTARii® Application Icon used to launch software

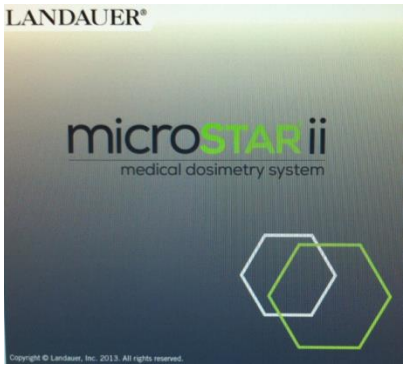


Figure 10: The MicroSTARii® software startup screen

As shown in Figure 11 below, you will then be prompted to Login to the system. If this is your first time launching the software, use the Landauer- provided default ADMIN Login (Username: admin and Password: starii), otherwise use your previously established ADMIN Login Username and Password.

Note: During the installation process you will change the default ADMIN login password. Notice your software's Unique Identifier code at the bottom of the screen. If ever asked for this code you can also find it on the About Screen of the MicroSTARii® software.

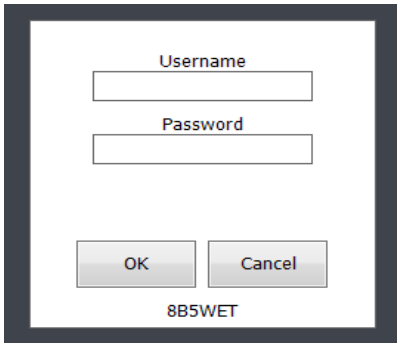


Figure 11: The MicroSTARii® software LOGIN screen

2 MicroSTARii® System Configuration (continued)

2.1 Startup microSTARii® Application Software (continued)

IMPORTANT NOTE REGARDING ADMINISTRATOR ACCOUNT

The ADMINISTRATOR login is by design restricted to administrative functions including the creation of USER accounts. You will not be able to operate the reader to obtain dosimetry measurements when logged in under the ADMINISTRATOR account. At a minimum you must create one ADVANCED OPERATOR account to conduct reader verification tests at installation, which is part of the installation protocol and an essential step in implementing a comprehensive reader QA program. Instructions on how to create an ADVANCED USER account are provided in Section 2.3: Create/Edit User Account(s). Additional details of how security features and user account privileges are implemented are covered in the MicroSTARii® User Manual.

2.2 Confirm Reader Settings and Assign Reader Name

Go to the Configure Screen and click on the Manage Reader button as shown by the arrow shown in Figure 12 below.

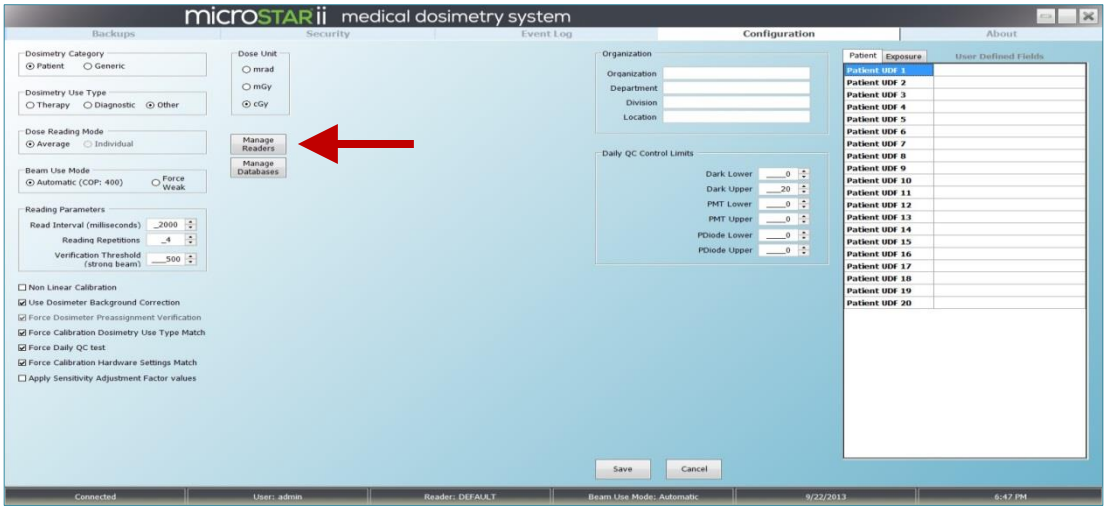


Figure 12: Configuration Screen showing Manage Reader button

2 MicroSTARii® System Configuration (continued)

2.2 Confirm Reader Settings and Assign Reader Name (continued)

In the window that pops up, shown in Figure 13, verify that the Reader Named Default (which should be the only reader listed for new installs where a prior reader has not been connected to the computer) has a Reader UID value listed in the table that corresponds to the last 4 digits of the barcode serial number at the back of your reader, and for newly installed readers, that the Current Hardware Settings ID is 1.

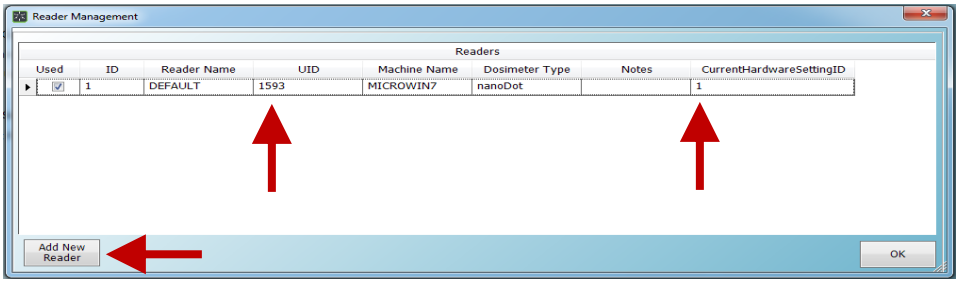


Figure 13: Reader Management Window showing UID and HW Settings ID

In the Reader Management window, click on the Add New Reader button as shown in Figure 13 to customize your reader identification. This is particularly important if you have more than one reader at your facility. The New Reader window will pop up as shown below in Figure 14. Enter a unique and descriptive Reader Name and click OK to update the reader database.

Figure 14: New Reader Window showing Reader name entered

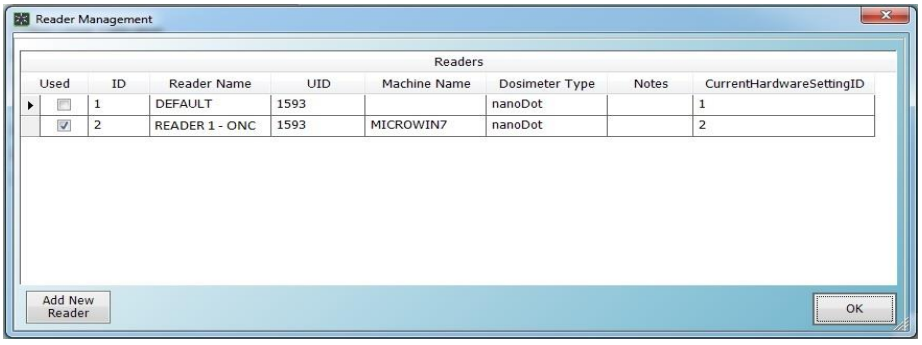


Figure 15: Reader Management window showing updated reader list and selection

2 MicroSTARii® System Configuration (continued)

2.3 Create / Edit User Account(s)

Once the reader has been properly configured and named you must next establish the correct USER accounts for your facility. To comply with HIPAA guidelines it is imperative that all operators of the MicroSTARii® system have their own individual login account to support security audits and traceability.

For your convenience the MicroSTARii® application has predefined User Account Security Profiles to facilitate the creation of USER accounts and the three default profiles are shown below. Note: Customized User Account Security Profiles can be created or edited while logged in under the ADMIN account.

Table 2 Pre-defined Account Security Profiles

SECURITY PROFILE	CATEGORY OF USE	RESTRICTIONS
Admin	Administration	Cannot operate reader, cannot modify reader factory hardware settings
Advanced Operator	High-Moderate Level Expert	Cannot create user accounts, cannot access advanced configuration settings, cannot modify reader factory hardware settings
Operator	Routine dosimetry user	Cannot access most configuration settings, cannot access certain advanced features such as Sensitivity Assessment, cannot modify reader factory hardware settings

To proceed with User Account SETUP, click on the SECURITY tab in the MicroSTARii® application software shown in Figure 16 below.

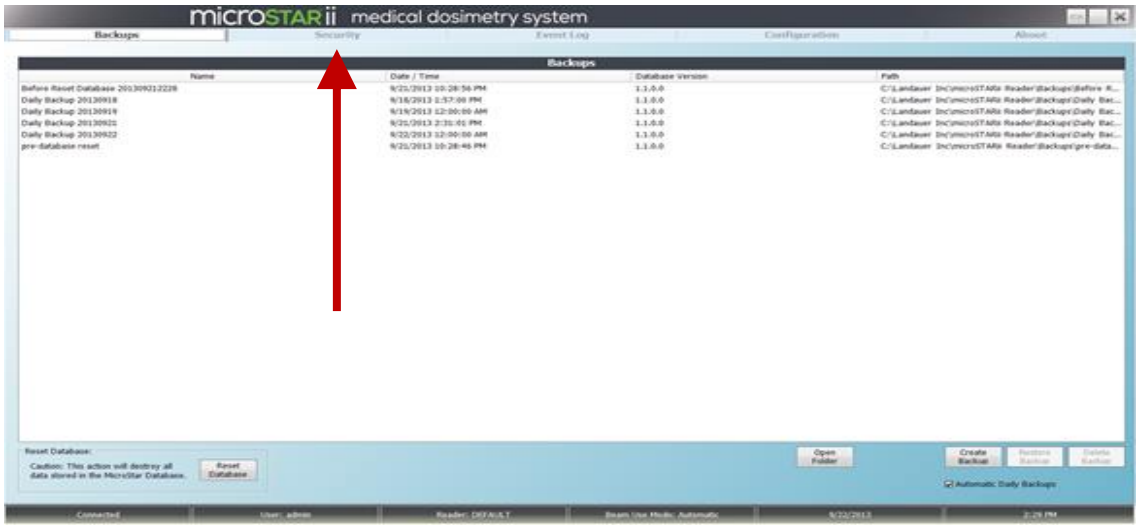


Figure 16: The ADMIN account default startup page.

2 MicroSTARii® System Configuration (continued)

2.3 Create / Edit User Account(s) (continued)

Perform the following sequence to establish site-specific User Accounts:

STEP 1:

Update the ADMINISTRATOR account settings by locating the Username ADMIN in the USERS table shown in Figure 17, and either double-click anywhere in the selected row (top arrow), or click the EDIT button (bottom arrow).

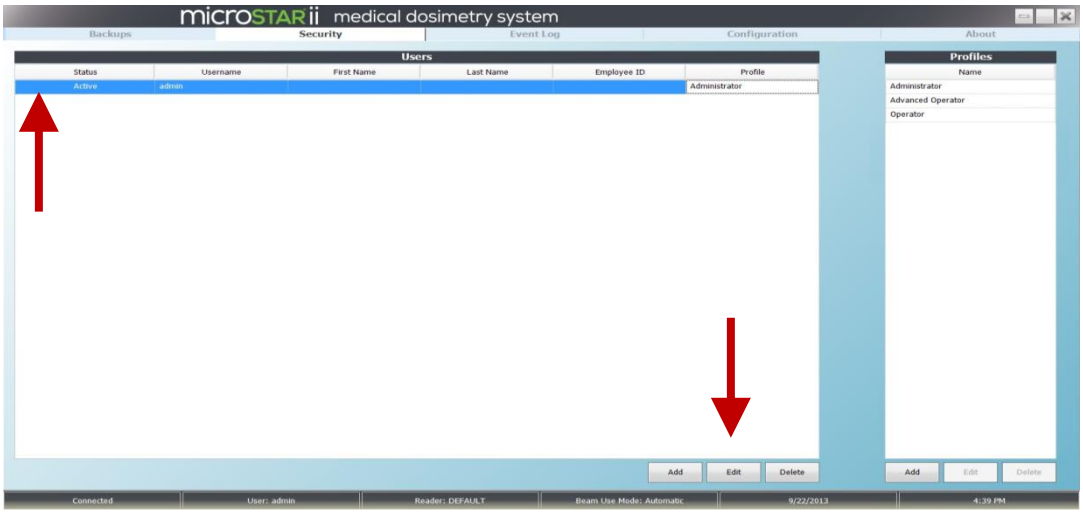


Figure 17: The ADMIN account default SECURITY settings and how to edit them.

When the Edit User window pops up, verify that the CAPS LOCK key is OFF, and then change the default password. Write it down temporarily. If available, enter the name and employee number of the designated System Administrator as shown in Figure 18 before clicking OK to update the ADMIN account configuration.

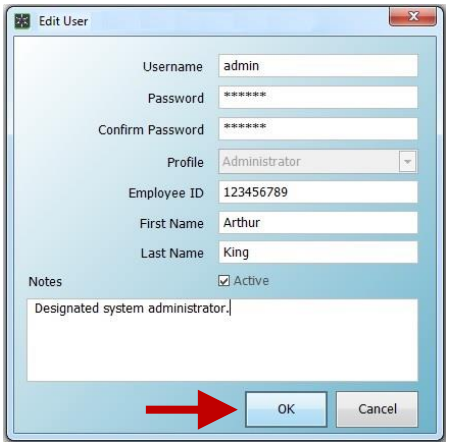


Figure 18: Edit User Pop-up window.

2 MicroSTARii® System Configuration (continued)

2.3 Create / Edit User Account(s) (continued)

The site-specific customization of your ADMIN account via assignment of administrator privileges to a specific individual is now complete. Verify that the USER account list reflects the correct demographics for the ADMIN account as shown in Figure 19. It is recommended that you log out and log back in to ensure that you can access the ADMIN account before proceeding with the installation. Contact Landauer Customer Service if you encounter problems.

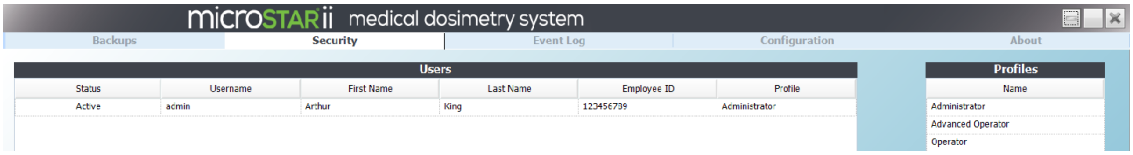


Figure 19: Updated ADMIN account settings in window

STEP 2

Create at least one (1) ADVANCED OPERATOR account for the individual who will be conducting the MicroSTARii® reader verification tests at installation. It is also generally recommended that the individual assigned to the ADMIN role also have an ADVANCED OPERATOR User account to verify reader configuration and performance.

To create an ADVANCED OPERATOR ACCOUNT, click on the ADD button as shown in Figure 20. Enter all required information in the New User window. Select ADVANCED OPERATOR from the Profile pull-down list. Click OK to add the New User.

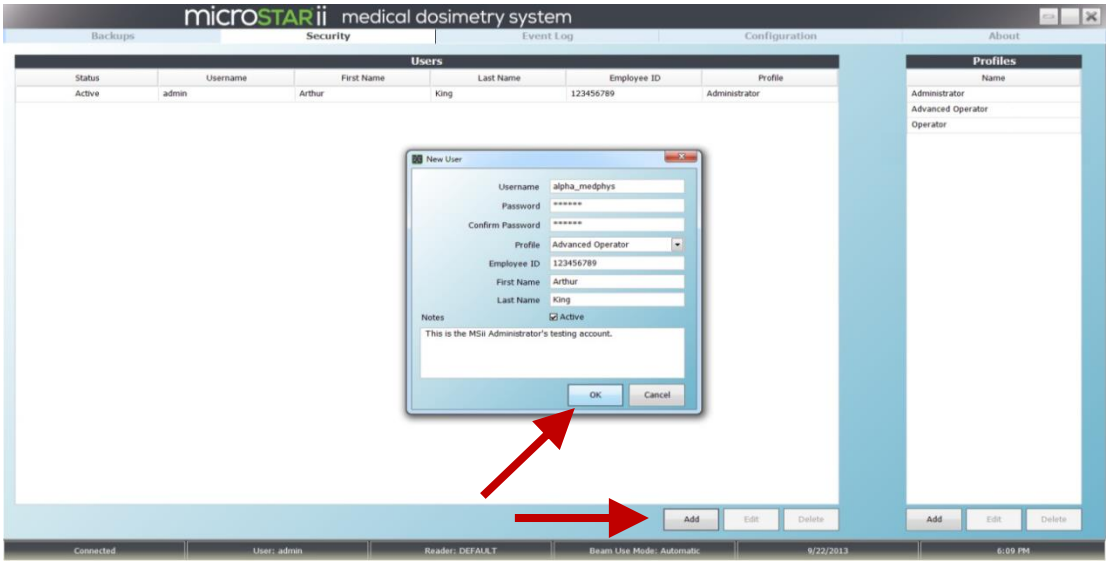


Figure 20: Creation of Advanced Operator account for reader installation testing.

2 MicroSTARii® System Configuration (continued)

2.3 Create / Edit User Account(s) (continued)

When the USER account list updates as shown below in Figure 21, verify the accuracy of the information listed.

Figure 21: List showing ADMIN and added ADVANCED OPERATOR account.

STEP 3 (Optional – can be deferred until after reader installation testing)

Create User accounts for all individuals who will be using the MicroSTARii® Medical Dosimetry System. You will need a designated Username, their First and Last Names, and their Employee #. Identify the security access privileges required for each user by consulting the list of default User Security Profiles listed in Table 2. For detailed instructions on creating and modifying user accounts and default security profiles, consult the MicroSTARii® User Manual.

Note: Once a user account is created you can only change the user's access privileges by re-assigning their account to a specific pre-defined security profile. You can create custom profiles or modify pre-existing profiles to account for the unique requirements of your users and the dosimetry applications at your facility. For more detailed information consult consult the MicroSTARii® User Manual.

2 MicroSTARii® System Configuration (continued)

2.4 Set Configuration Screen Options

STEP 1

While logged in under the ADMIN account, enter Organization demographic data in the appropriate fields on the Configuration Screen as shown by Step 1 in Figure 22 below.

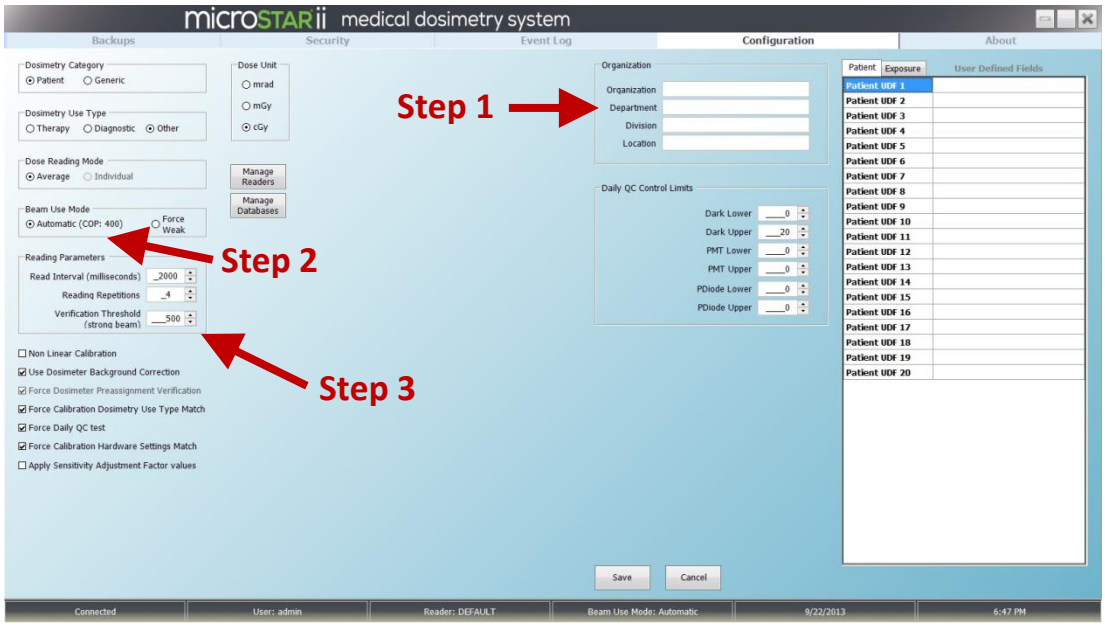


Figure 22: Organization demographic fields on the Configuration Screen.

An example of Organization demographic data is shown below in Figure 23 below.

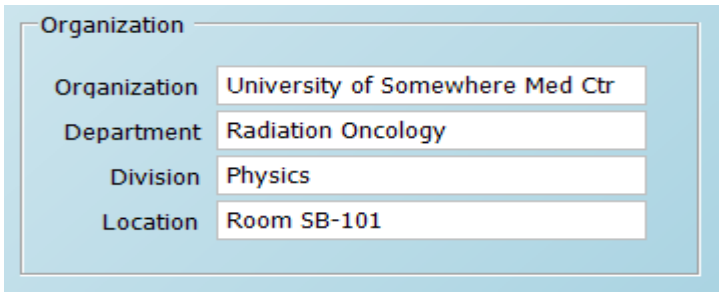


Figure 23: An example showing fictitious Organization demographic data.

2 MicroSTARii® System Configuration (continued)

2.4 Set Configuration Screen Options (continued)

IMPORTANT NOTE REGARDING ORGANIZATION INFO:

The Organization demographics fields cannot be modified by users other than ADMIN and care should be taken to ensure that the Organization demographic data is accurately represented at each location and for each reader in service at your facility. This data will be subsequently included with every dosimetry database record to identify the origin of the data and is also printed at the top of Patient Dose Reports generated.

STEP 2

As shown by Step 2 in Figure 22 and below in Figure 24, confirm that the Beam Use Mode selection is AUTOMATIC and that the COP value shown in parentheses corresponds to that shown on the MicroSTARii® reader Factory Test Results sheet that came with your reader.

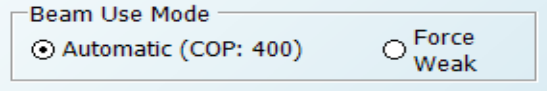


Figure 24: Beam Use Mode options

An example of data reported on the Factory Test Result Sheet is shown in Figure 28.

STEP 3

The default Verification Threshold for unexposed nanoDots read using the strong beam readout mode is 500 raw counts as shown in Figure 22, but this value can be lowered to the desired threshold based on the protocols in use at your institution. However, it should be noted that unexposed dosimeters that have been manufactured within the last six months prior to verification, typically yield strong beam raw count values below 200.

2 MicroSTARii® System Configuration (continued)

2.4 Set Configuration Screen Options (continued)

STEP 3 (continued)

IMPORTANT NOTES:

1. Most of the remaining settings on the Configuration page can be modified on an "as needed" basis by individual users during normal operation of the reader. Additional details of these options and their impact on reader performance, are covered in the MicroSTARii® User Manual.

2. The Daily QC Control Limit value fields on the Configuration Screen, which are shown below in Figure 25, will be updated/populated based on the results of the Intrinsic Measurements Control Limit test performed during reader installation testing on site, prior to clinical use.

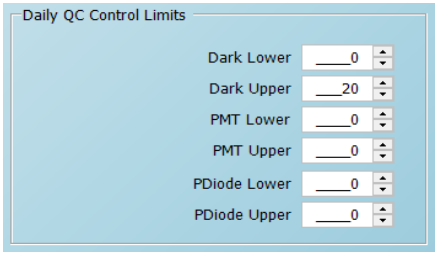


Figure 25: Daily QC Control Limits

3 MicroSTARii® Reader Tests at Installation

RATIONALE

Basic reader performance must be validated at installation of the reader by following the Landauer-recommended Installation Test protocol, a MANDATORY requirement prior to clinical use of the reader in medical dosimetry applications. This protocol establishes the MINIMUM level of reader tests that must be performed prior to clinical use. Additional reader performance tests may be conducted at installation of the reader prior to clinical use, or at any time thereafter, at the discretion of the Qualified Medical or Health Physicist responsible for oversight of the MicroSTARii® Reader QA Program at your facility.

3 MicroSTARii® Reader Tests at Installation

IMPORTANT NOTE: At any time during Installation Testing you may consult with Landauer Technical Support for assistance in implementing the MicroSTARii® QA Program.

PROTOCOL OVERVIEW

The Installation Test protocol is generally comprised of two Parts. Part 1 is required of both diagnostic and therapy customers and Part 2 is a special additional clinical calibration performed under specific conditions that mimic certain medical dosimetry applications in radiation oncology.

Part 1 of the Installation Test protocol, depicted in Figure 26 has five steps:

A. Establish control limits for reader Intrinsic tests (20 reading cycles)
B. Perform reader intrinsic performance test (5 reading cycles)
C. Conduct nanoDot reading reproducibility test (10 readings)
D. Perform reader calibration using Landauer-supplied Calibration Set
E. Perform a post-calibration QC check to verify the calibration

The reader intrinsic performance tests assess the stability of reader electronics, PMT and LED, and do not require a dosimeter. The nanoDot reading reproducibility test assesses the reader's performance under typical dosimeter readout conditions, using a high dose constancy nanoDot supplied by Landauer. The NIST-traceable calibration is performed using dosimeters (Calibration and QC Sets) supplied by Landauer. The choice of beam quality for calibration is dictated by the application. Diagnostic customers must use a Landauer-supplied NIST-traceable 80 kVp Calibration and QC Set that has been exposed on a 30 x 30 x 10 cm acrylic phantom. Therapy customers must use a Landauer-supplied NIST-traceable Cs-137 (662 keV) Calibration and QC Set that has been exposed at a depth of d_{max} on acrylic support arms.

Part 2 of the Installation Test protocol, depicted in Figure 27 requires specific exposure conditions that are depicted in Figure 57.

3 MicroSTARii® Reader Tests at Installation (continued)

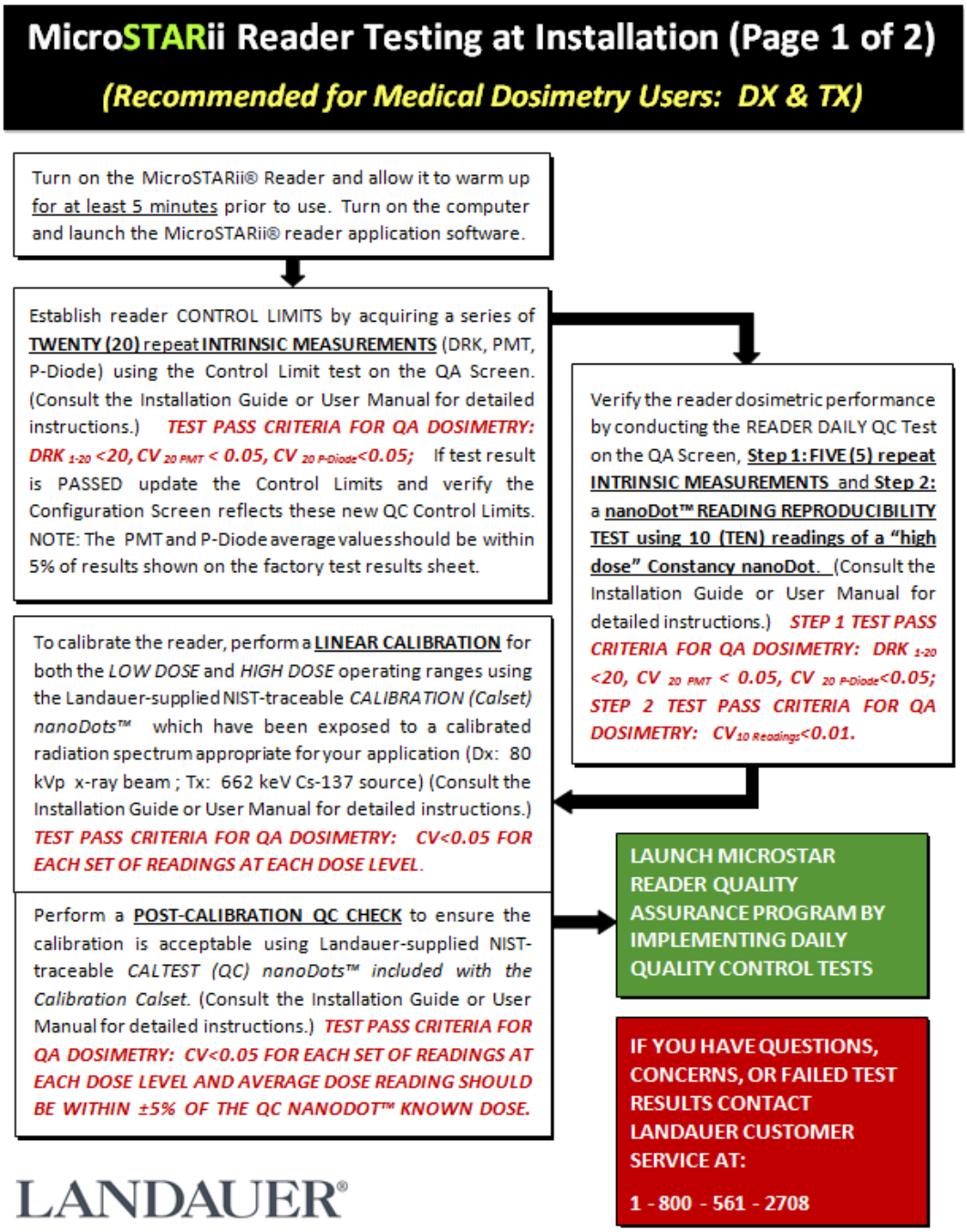

MicroSTARii Reader Testing at Installation (Page 1 of 2)
(Recommended for Medical Dosimetry Users: DX & TX)
Turn on the MicroSTARii® Reader and allow it to warm up for at least 5 minutes prior to use. Turn on the computer and launch the MicroSTARii® reader application software.
Establish reader CONTROL LIMITS by acquiring a series of TWENTY (20) repeat INTRINSIC MEASUREMENTS (DRK, PMT, P-Diode) using the Control Limit test on the QA Screen. (Consult the Installation Guide or User Manual for detailed instructions.) TEST PASS CRITERIA FOR QA DOSIMETRY: DRK 1-20 <20, CV 20 PMT < 0.05, CV 20 P-Diode<0.05; If test result is PASSED update the Control Limits and verify the Configuration Screen reflects these new QC Control Limits. NOTE: The PMT and P-Diode average values should be within 5% of results shown on the factory test results sheet.
Verify the reader dosimetric performance by conducting the READER DAILY QC Test on the QA Screen, Step 1: FIVE (5) repeat INTRINSIC MEASUREMENTS and Step 2: a nanoDot™ READING REPRODUCIBILITY TEST using 10 (TEN) readings of a "high dose" Constancy nanoDot. (Consult the Installation Guide or User Manual for detailed instructions.) STEP 1 TEST PASS CRITERIA FOR QA DOSIMETRY: DRK 1-20 <20, CV 20 PMT < 0.05, CV 20 P-Diode<0.05; STEP 2 TEST PASS CRITERIA FOR QA DOSIMETRY: CV10 Readings<0.01.
To calibrate the reader, perform a LINEAR CALIBRATION for both the LOW DOSE and HIGH DOSE operating ranges using the Landauer-supplied NIST-traceable CALIBRATION (Calset) nanoDots™ which have been exposed to a calibrated radiation spectrum appropriate for your application (Dx: 80 kVp x-ray beam ; Tx: 662 keV Cs-137 source) (Consult the Installation Guide or User Manual for detailed instructions.) TEST PASS CRITERIA FOR QA DOSIMETRY: CV<0.05 FOR EACH SET OF READINGS AT EACH DOSE LEVEL.
Perform a POST-CALIBRATION QC CHECK to ensure the calibration is acceptable using Landauer-supplied NIST-traceable CALTEST (QC) nanoDots™ included with the Calibration Calset. (Consult the Installation Guide or User Manual for detailed instructions.) TEST PASS CRITERIA FOR QA DOSIMETRY: CV<0.05 FOR EACH SET OF READINGS AT EACH DOSE LEVEL AND AVERAGE DOSE READING SHOULD BE WITHIN ±5% OF THE QC NANODOT™ KNOWN DOSE.
LANDAUER®
LAUNCH MICROSTAR READER QUALITY ASSURANCE PROGRAM BY IMPLEMENTING DAILY QUALITY CONTROL TESTS
IF YOU HAVE QUESTIONS, CONCERNS, OR FAILED TEST RESULTS CONTACT LANDAUER CUSTOMER SERVICE AT:
1 - 800 - 561 - 2708

Figure 26: Installation Testing Flowchart Part 1: Diagnostic and Therapy Users

3 MicroSTARii® Reader Tests at Installation (continued)

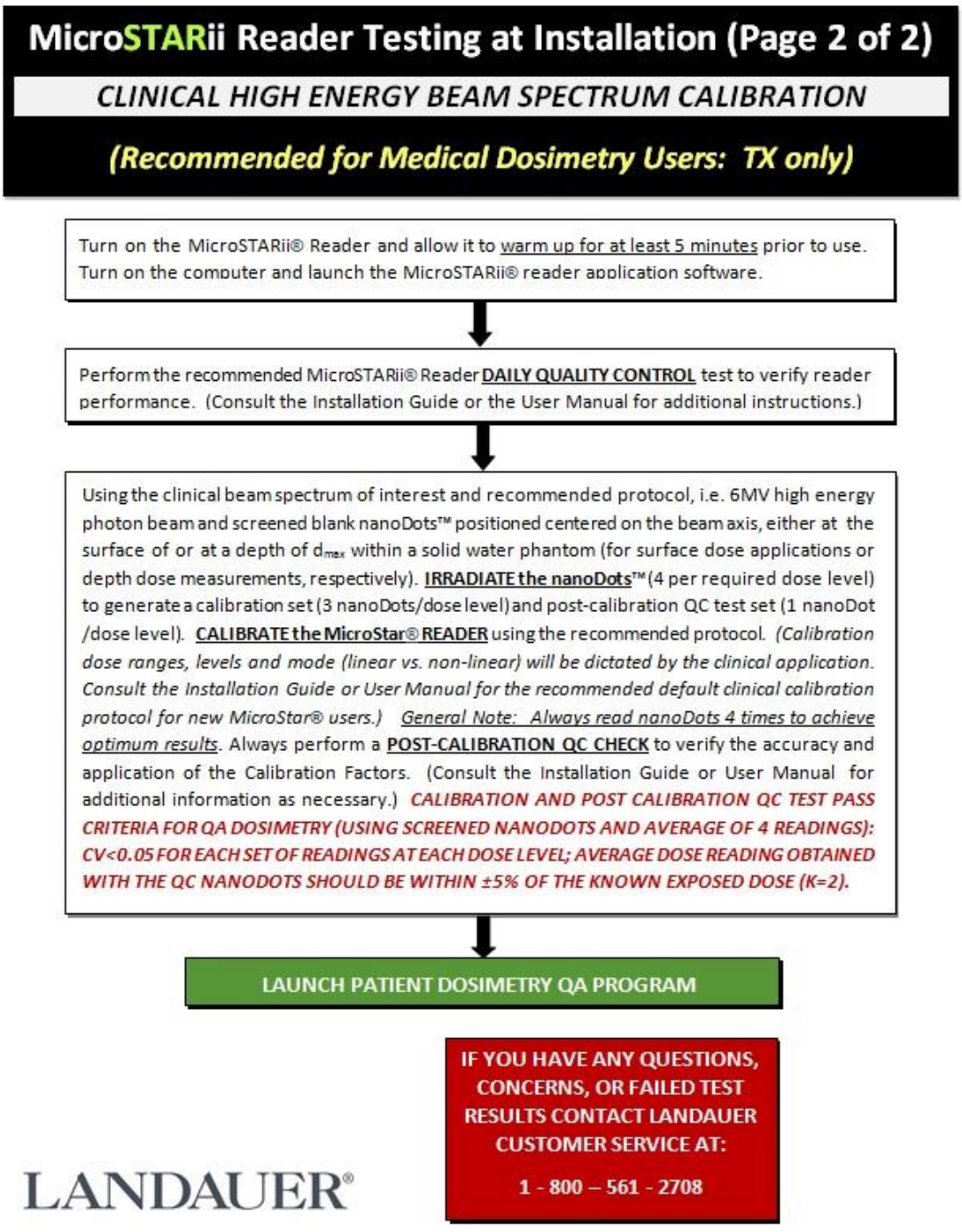

MicroSTARii Reader Testing at Installation (Page 2 of 2)
CLINICAL HIGH ENERGY BEAM SPECTRUM CALIBRATION
(Recommended for Medical Dosimetry Users: TX only)
Turn on the MicroSTARii® Reader and allow it to warm up for at least 5 minutes prior to use. Turn on the computer and launch the MicroSTARii® reader application software.
Perform the recommended MicroSTARii® Reader DAILY QUALITY CONTROL test to verify reader performance. (Consult the Installation Guide or the User Manual for additional instructions.)
Using the clinical beam spectrum of interest and recommended protocol, i.e. 6MV high energy photon beam and screened blank nanoDots™ positioned centered on the beam axis, either at the surface of or at a depth of d_{max} within a solid water phantom (for surface dose applications or depth dose measurements, respectively). IRRADIATE the nanoDots™ (4 per required dose level) to generate a calibration set (3 nanoDots/dose level) and post-calibration QC test set (1 nanoDot /dose level). CALIBRATE the MicroStar® READER using the recommended protocol. (Calibration dose ranges, levels and mode (linear vs. non-linear) will be dictated by the clinical application. Consult the Installation Guide or User Manual for the recommended default clinical calibration protocol for new MicroStar® users.) General Note: Always read nanoDots 4 times to achieve optimum results. Always perform a POST-CALIBRATION QC CHECK to verify the accuracy and application of the Calibration Factors. (Consult the Installation Guide or User Manual for additional information as necessary.) CALIBRATION AND POST CALIBRATION QC TEST PASS CRITERIA FOR QA DOSIMETRY (USING SCREENED NANODOTS AND AVERAGE OF 4 READINGS): CV<0.05 FOR EACH SET OF READINGS AT EACH DOSE LEVEL; AVERAGE DOSE READING OBTAINED WITH THE QC NANODOTS SHOULD BE WITHIN ±5% OF THE KNOWN EXPOSED DOSE (K=2).
LAUNCH PATIENT DOSIMETRY QA PROGRAM
IF YOU HAVE ANY QUESTIONS, CONCERNS, OR FAILED TEST RESULTS CONTACT LANDAUER CUSTOMER SERVICE AT:
1 - 800 – 561 - 2708
LANDAUER®

Figure 27: Installation Testing Flowchart Part 2: Therapy Users only

3 MicroSTARii® Reader Tests at Installation (continued)

PRE-TEST PREPARATIONS

STEP 1: Locate the Factory Test Summary sheet for your reader prior to commencing Installation Testing.

The Installation Tests conducted on site are a crucial component in the MicroSTARii® Reader QA Program, whose foundation is based on in-depth reader factory testing at the time of manufacture. A summary of these factory test results is provided with each reader. An excerpt from a Factory Test Result Sheet is shown in Figure 28 below.

LANDAUER

MicroSTARii Reader - Manufacturing QA Test Results

READER SERIAL #: TEST PERFORMED BY:

TEST DATE: SIGNATURE:

READER SETTINGS	
Firmware Version:	mms 2.1
Crossover Point:	299
CALIBRATION FACTOR Cs-137 (662 keV)	
Low Dose (counts/mrad):	3.873
High Dose (counts/mrad):	0.645
LOWER LIMIT OF DETECTION (mrad)	
Low Dose:	1.06
High Dose:	3.08
NANODOT READING REPEATABILITY @≥ 50cGy	
Stationary Repeatability %CV:	0.55%
Moving Repeatability %CV:	0.64%
INTRINSIC MEASUREMENTS	
Maximum Dark Counts:	3
Average PMT Counts:	4865
PMT %CV:	1.103%
Average Photodiode Counts:	1477
Photodiode %CV:	0.871%
LIGHT LEAKAGE	
Maximum Dark Counts:	2
LINEARITY	
Slope:	0.997
R-Squared:	0.9996
Average Bias:	-2.04%

microSTARii medical dosimetry system

Figure 28: Sample MicroSTARii Reader Manufacturing QA Test Report

IMPORTANT NOTE:

If your reader is operating correctly and has not been damaged during shipment, its performance at installation should be comparable to that measured during manufacturing QA Testing. Note in particular the Low and High Dose calibration factors and the PMT and P-Diode average baseline values from your test sheet and compare with the results obtained during Installation Testing.

3 MicroSTARii® Reader Tests at Installation (continued)

PRE-TEST PREPARATIONS (continued):

STEP 2: Locate the Landauer-supplied NIST-traceable Constancy, Calibration and QC dosimeters.

STEP 3: Make sure your reader has been turned ON for at least 5 minutes

STEP 4: Login to the ADVANCED OPERATOR account for the USER who will be conducting Installation Testing

STEP 5: Check that the READER connection status shows CONNECTED (see bottom frame, left-most corner).

INSTALLATION TEST INSTRUCTIONS:

PART 1A: Establishing Control Limits for Step 1 of Daily QC Test

Navigate to the QA Screen and click the START button beside Verify/Establish QC Control Limits, as shown in Figure 29.

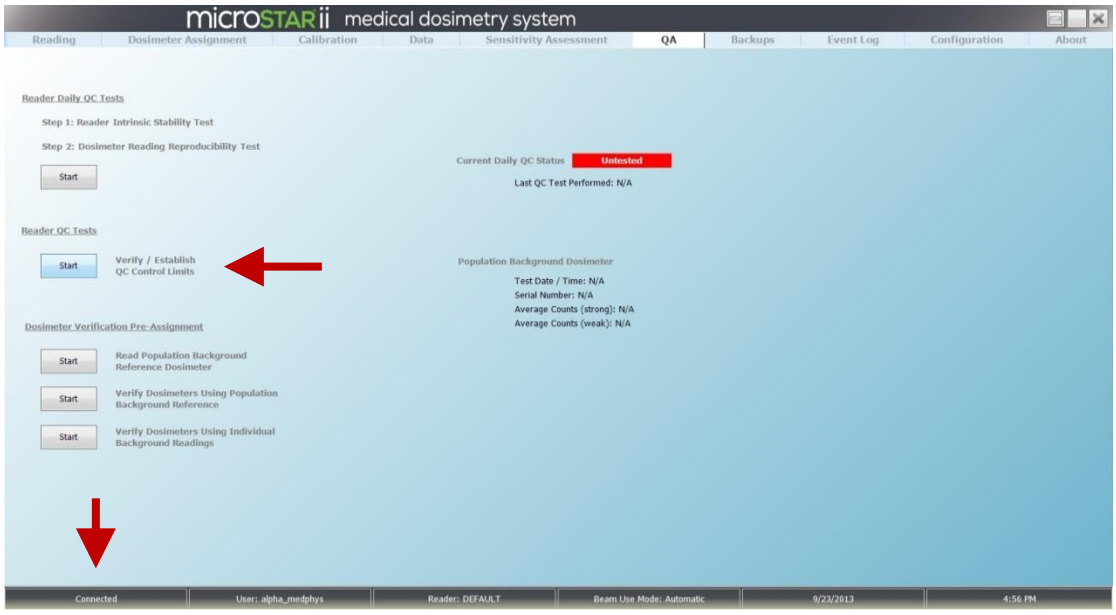


Figure 29: Reader QA Screen as initially displayed during installation

3 MicroSTARii® Reader Tests at Installation (continued)

INSTALLATION TEST INSTRUCTIONS:

As shown in Figure 30 below, click OK when prompted by the dialog box asking for confirmation that the reader drawer is empty and does not contain a dosimeter. (Verify if necessary.)

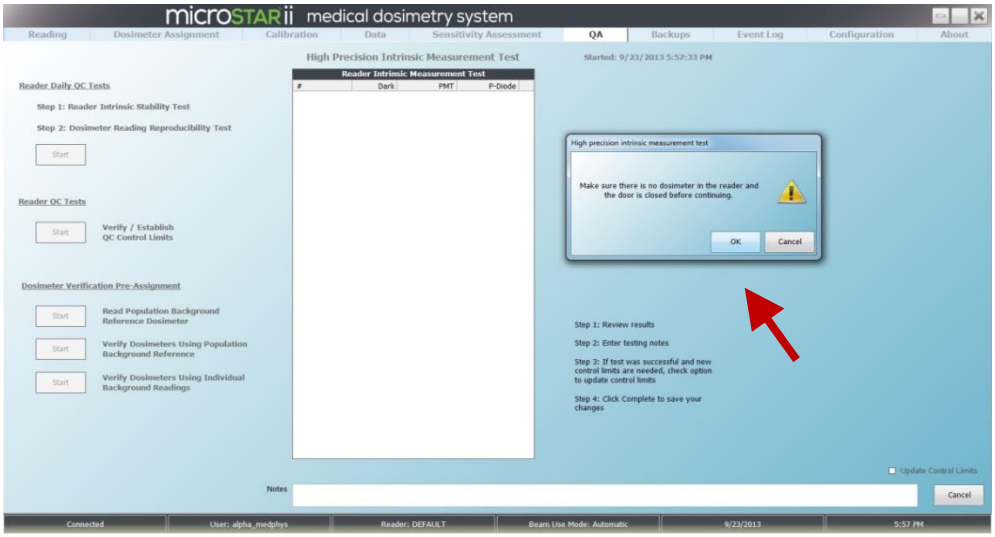


Figure 30: QA Screen Control Limit Test – Verify No Dosimeter in Drawer

A series of 20 cycles of reader Intrinsic Measurements will be collected in the following sequence: Dark Counts, PMT Counts and Photodiode Counts. When all data has been acquired the result status will be reflected at the bottom of the results table by a bar colored GREEN or RED for a test result that is PASSED or FAILED, respectively, as shown in Figure 31 below.

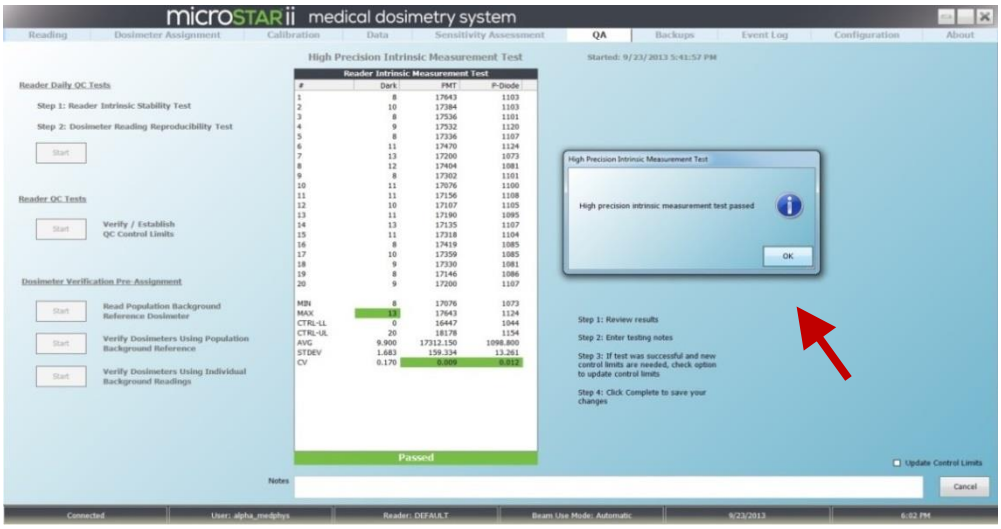


Figure 31: QA Screen Control Limit Test – Test Result Acknowledgment

Click OK in the displayed dialog box to acknowledge the test result.

3 MicroSTARii® Reader Tests at Installation (continued)

Check the Update Control Limits checkbox as shown below in Figure 32 and click COMPLETE to save the results, generate a report, and update the Control Limits depicted on the Configuration Screen, and the PASS/FAIL criteria for the Daily QC Test.

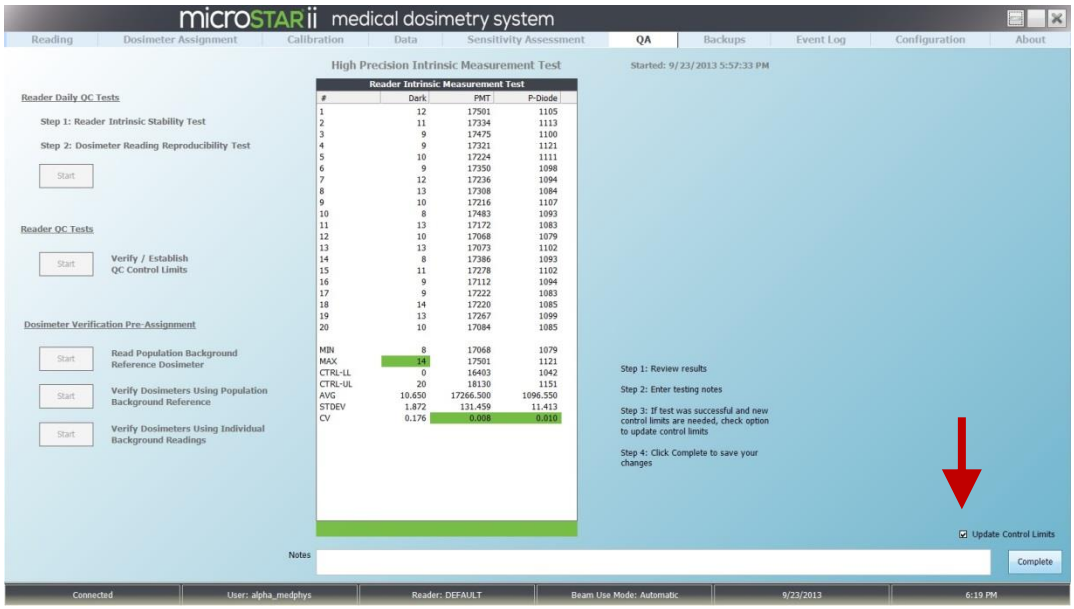


Figure 32: QA Screen Control Limit Test – Option to SAVE new Control Limits

A dialog box is displayed as shown in figure 33 below, confirming that the test results have been saved and that new Control Limits have been saved.

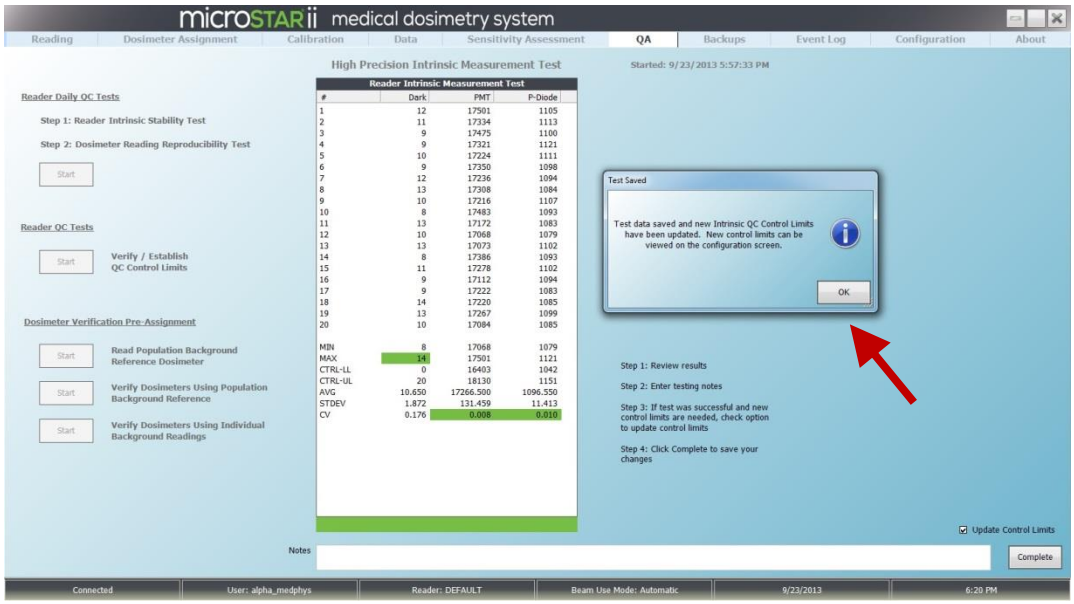

microSTARii medical dosimetry system
Test Saved
Test data saved and new Intrinsic QC Control Limits have been updated. New control limits can be viewed on the configuration screen.
OK
Update Control Limits
Complete

Figure 33: QA Screen Control Limit Test – Confirmation Control Limits Saved

3 MicroSTARii® Reader Tests at Installation (continued)

Go to the Configuration Screen and verify that the Control Limits have been correctly updated as shown in Figure 34 below.

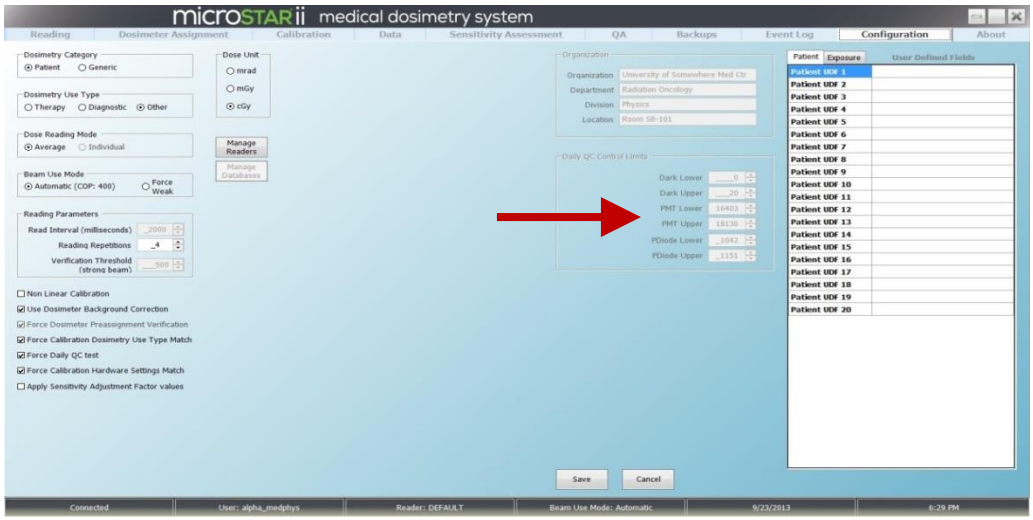


Figure 34: QA Screen Control Limit Test – Verify Limits on Configuration Screen

PART 1 B & C: Perform the Daily Quality Control (QC) Test

Return to the QA Screen and as shown in Figure 35 below click START to commence the reader Daily QC test. Step 1 involves acquisition of five (5) cycles of Intrinsic Measurement data, evaluated using the previously saved Control Limits. Step 2 involves reading a high dose constancy nanoDot 10 times in sequence to verify that dosimeter reading reproducibility is acceptable, i.e. the coefficient of variation (CV) across all 10 readings is ≤ 1.0%.

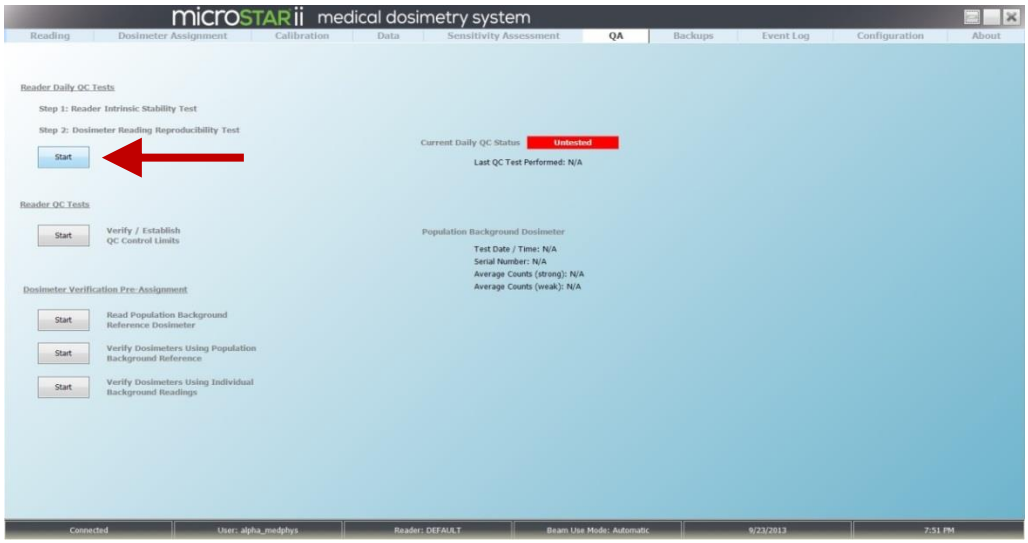


Figure 35: QA Screen Daily QC Test - Status is “Untested” at start

3 MicroSTARii® Reader Tests at Installation (continued)

As shown in Figure 36 below, a dialog box will display asking you to check that there is no dosimeter in the reader drawer during Step 1 of the Daily QC Test. Click OK after verifying that the drawer is empty. Five (5) cycles of Intrinsic Measurement data will then be collected.

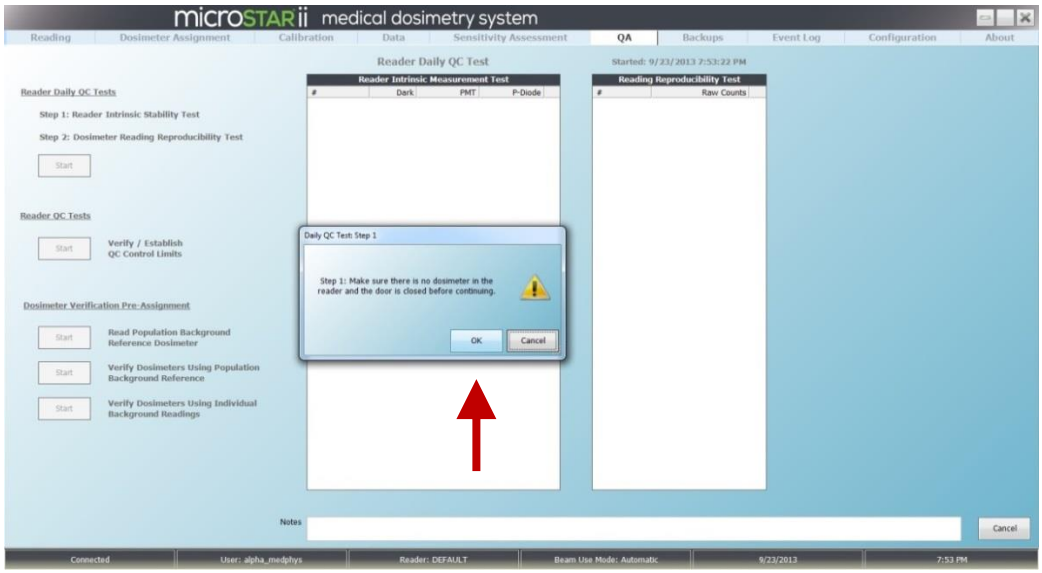


Figure 36: QA Screen Daily QC Test Step 1- Verify Reader Drawer Empty

When the data acquisition for Step 1 is complete, as shown in Figure 37 below, the result status is reflected via a color-coded STATUS BAR: green for PASSED, red for FAILED (not shown).

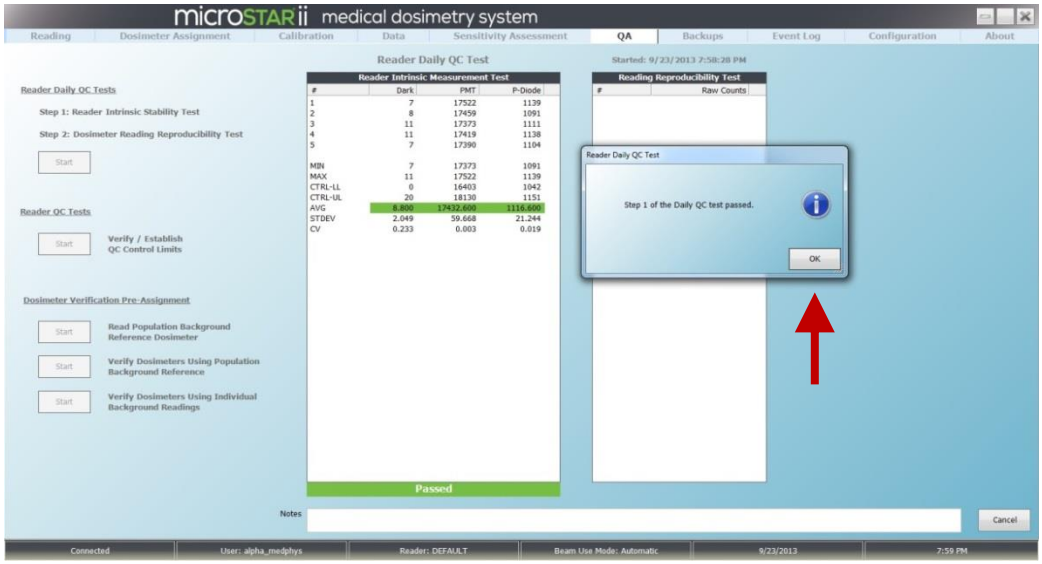


Figure 37: QA Screen Daily QC Test Step 1 – Acknowledge Test Result

If the result is PASSED, a dialog box confirming the successful completion of the test will be displayed. Click OK to acknowledge the message and to continue to Step 2.

3 MicroSTARii® Reader Tests at Installation (continued)

Select one of the high dose Constancy nanoDots that came with your reader and using the barcode scanner, scan the dosimeter serial number as shown in Figure 38 below. Click OK to start Test 2.

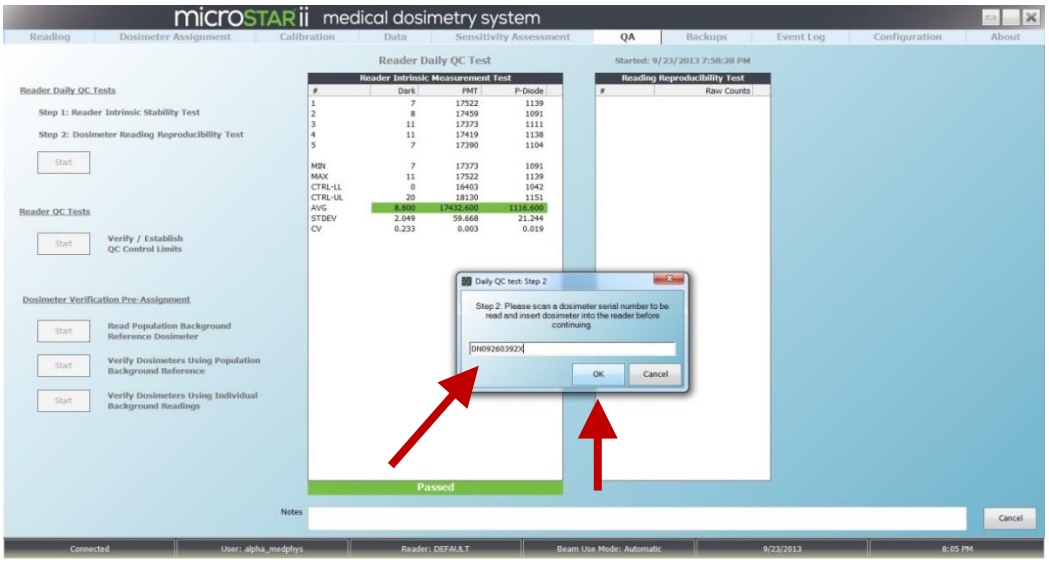


Figure 38: QA Screen Daily QC Test Step 2 – Prompt for dosimeter serial #

Ten (10) nanoDot readings will be acquired in sequence and the coefficient of variation (CV) will be computed across all 10 readings. For a Test 2 status result of PASSED, the computed CV must be ≤ 1.0 %.

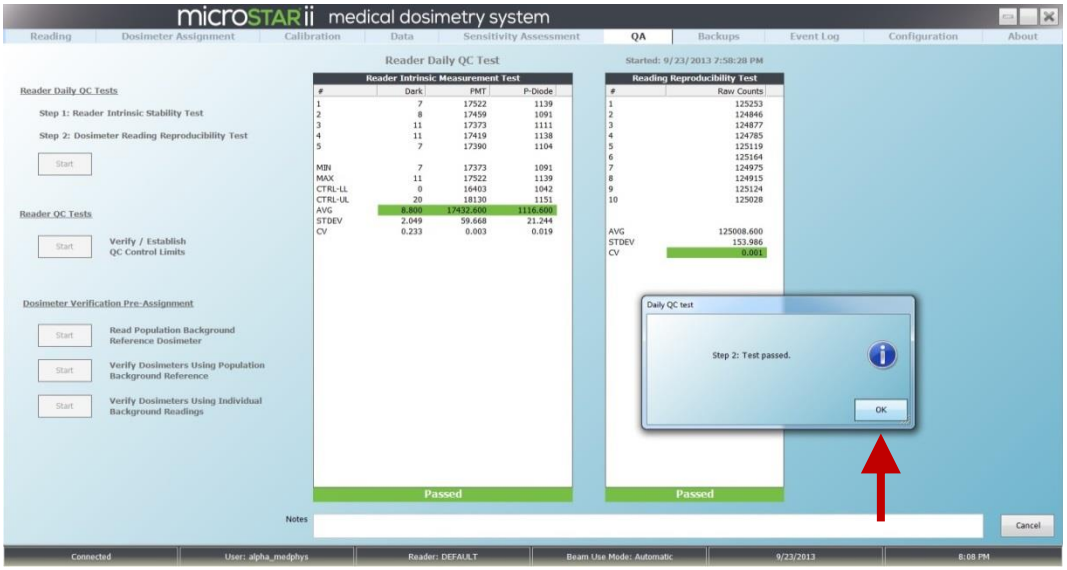


Figure 39: QA Screen Daily QC Test Step 2 – Acknowledge Test Result

If Test 2 passes, a dialog box will be launched as shown in Figure 39.

3 MicroSTARii® Reader Tests at Installation (continued)

Click OK to acknowledge the test result is PASSED. To SAVE the result and generate a Daily QC Test report, click the COMPLETE button at the bottom right of the screen as shown in Figure 40.

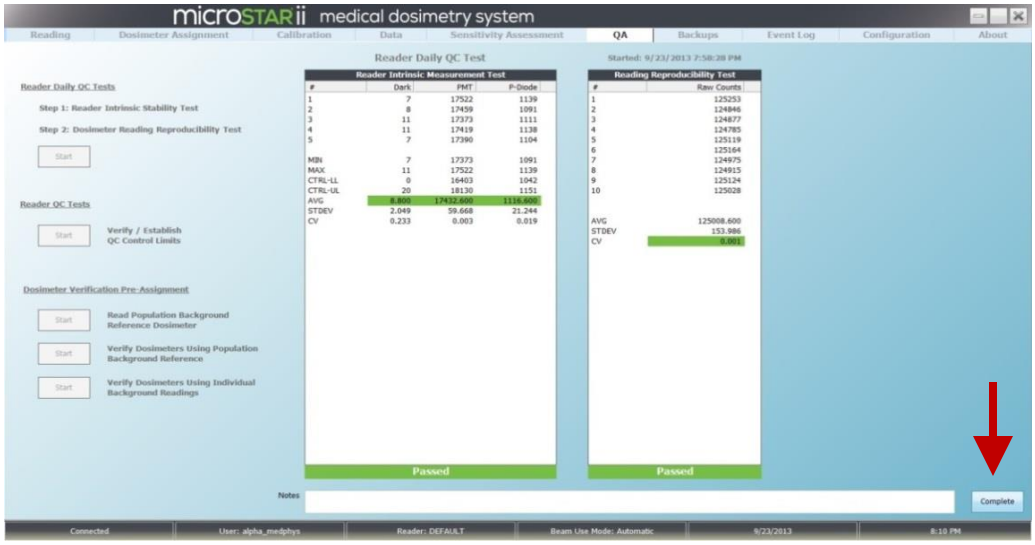


Figure 40: QA Screen Daily QC Test Step 2 – Complete and save results

At the completion of the test the Daily QC status will be updated on the Reading Screen as well as on the QA Screen, as shown below in the case where the test status is PASSED as shown in Figure 41.

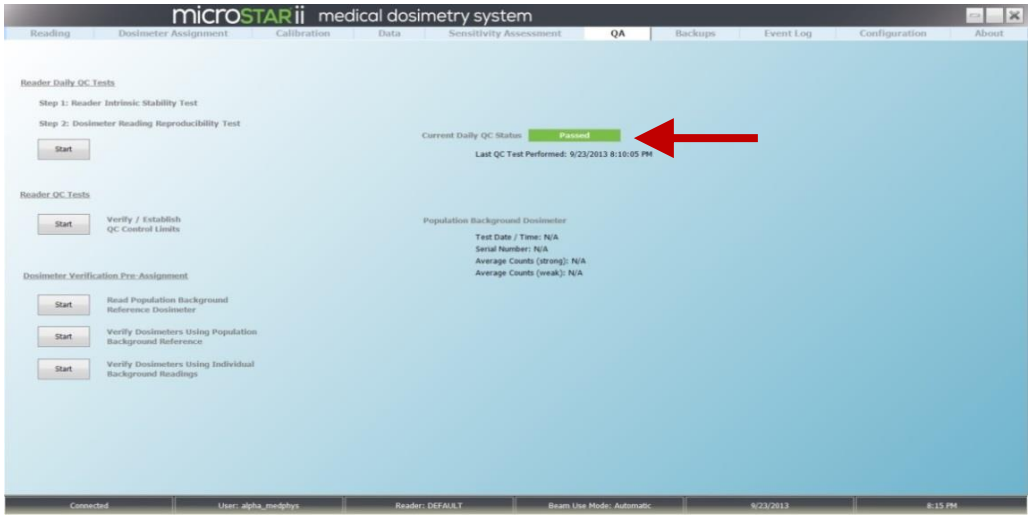


Figure 41: QA Screen reflecting current Daily QC Test Status of PASSED

Reader QA Test reports are available in PDF, XLS, and XML formats and can be accessed via the MicroSTARii® Reports shortcut on the Desktop or by navigating to: C:\Program Files\Landauer Inc\microSTARii Reader\Reports.
Sample reports are shown in Figures 42 and 43.

3 MicroSTARii® Reader Tests at Installation (continued)

University of Somewhere Med Ctr — Radiation Oncology

MicroSTARii Control Limit Test Report

Date / Time of Test: 09/23/2013 06:00:54 PM
Reader: DEFAULT
Test Peformed by: alpha_medphys

High Precision Intrinsic Measurement Test — **Control Limits Updated: Yes**

Reading	Dark Counts	PMT Counts	P-Diode Counts
1	12	17501	1105
2	11	17334	1113
3	9	17475	1100
4	9	17321	1121
5	10	17224	1111
6	9	17350	1098
7	12	17236	1094
8	13	17308	1084
9	10	17216	1107
10	8	17483	1093
11	13	17172	1083
12	10	17068	1079
13	13	17073	1102
14	8	17386	1093
15	11	17278	1102
16	9	17112	1094
17	9	17222	1083
18	14	17220	1085
19	13	17267	1099
20	10	17084	1085
Min	8	17068	1079
Max	14	17501	1121
CTRL-LL	**0**	**16403**	**1042**
CTRL-UL	**20**	**18130**	**1151**
AVG	10.650	17266.500	1096.550
STDEV	1.872	131.459	11.413
CV	0.176	0.008	0.010
Test Result	PASSED	PASSED	PASSED

Comments:

Signature of Reviewer: _____ Date Reviewed: _____

IMPORTANT NOTE: Reader Control Limits should only be changed when justified, i.e. after reader repair or preventative maintenance consistent with QA "Best Practices". Contact Landauer Customer Service at 1-800-561-2708 if reader Daily QC results exceed Control Limits.

Figure 42: Sample Intrinsic Measurements Control Limit Test Report

3 MicroSTARii® Reader Tests at Installation (continued)

University of Somewhere Med Ctr — Radiation Oncology

MicroSTARii Daily QC Test Report

Date / Time of Test: 09/23/2013 08:10:05 PM
Reader: DEFAULT
Test Peformed by: alpha_medphys

STEP 1: Daily Intrinsic Measurement Test

Reading	Dark Counts	PMT Counts	P-Diode Counts
1	7	17522	1139
2	8	17459	1091
3	11	17373	1111
4	11	17419	1138
5	7	17390	1104
Min	7	17373	1091
Max	11	17522	1139
CTRL-LL	**0**	**16403**	**1042**
CTRL-UL	**20**	**18130**	**1151**
AVG	8.800	17432.600	1116.600
STDEV	2.049	59.668	21.244
CV	0.233	0.003	0.019
Test Result	PASSED	PASSED	PASSED

STEP 2: Reading Reproducibility Test

Reading	Element Counts
1	125253
2	124846
3	124877
4	124785
5	125119
6	125164
7	124975
8	124915
9	125124
10	125028
AVG	125008.602
STDEV	153.986
CV	0.001
Test Result	PASSED

Comments:

Signature of Reviewer: _____ Date Reviewed: _____

IMPORTANT NOTE: Reader Control Limits should only be changed when justified, i.e. after reader repair or preventative maintenance consistent with QA "Best Practices".
Contact Landauer Customer Service at 1-800-561-2708 if reader Daily QC results exceed Control Limits.

Figure 43: Sample Daily Quality Control Test Report

3 MicroSTARii® Reader Tests at Installation (continued)

IMPORTANT NOTE:

It is recommended that you maintain all QC record data in either electronic or hardcopy format, for the life of the reader.

PART 1D: Reader Calibration using a NIST-Traceable Calibration Set

Go to the Calibration Screen to perform a reader calibration using the NIST-traceable Calibration Set from Landauer. Diagnostic users will use an 80 kVp Calibration Set, Therapy users will use a Cs-137 (662 keV) Calibration Set.

Note that there are two pre-installed DEFAULT calibrations listed as shown in Figure 44. As these are NOT APPROPRIATE for dosimetry use, you must perform reader calibration(s) to verify your reader's performance and to establish clinical dosimetry calibration factors.

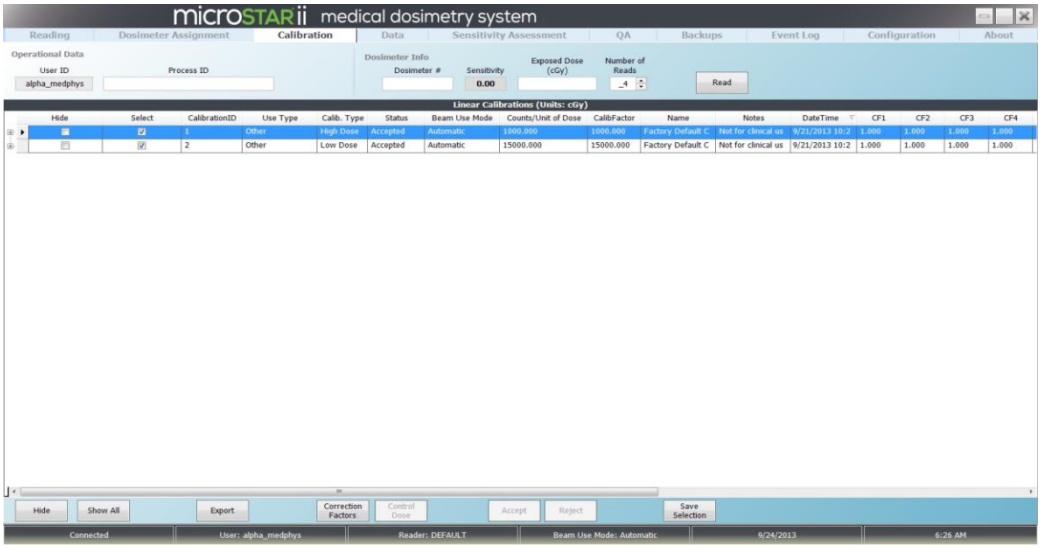


Figure 44: Calibration screen showing default calibrations not for clinical use.

Go to the Configuration Screen and verify that the Beam Use Mode setting is AUTOMATIC (Figure 45) and selected units are millirad (mrad) (Figure 46) and click SAVE before exiting.

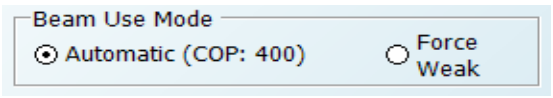


Figure 45: Beam Use Mode selection

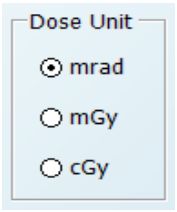


Figure 46: Units selection

3 MicroSTARii® Reader Tests at Installation (continued)

Return to the Calibration Screen and under OPERATIONAL DATA, enter a Process ID that is descriptive of the calibration condition. An example is shown below in Figure 47. There will be an opportunity to affix a NOTE to the calibration just before ACCEPTING and completing the calibration.

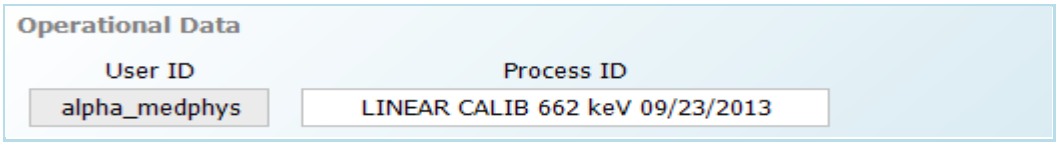


Figure 47: Calibration Screen Operational Data fields

Locate your Calibration Set and arrange the envelopes (containing 3 nanoDots each) by increasing dose, keeping "Low Dose" and "High Dose" ranges separate. The dosimeters at each dose level will be read to compute LINEAR CALIBRATION FACTORS for the Low Dose and High Dose ranges.

PROCEDURE:

Perform steps 1-8 for the Low Dose and High Dose Calibration Dosimeters.

1. Scan in the selected dosimeter serial number into the field shown below. The Sensitivity field should automatically update.
2. Enter the known exposed dose in the Exposed Dose field depicted in Figure 48, for the dosimeter being read, which can be obtained from the "Delivered Exposure" column labeled **SDE** (Shallow Dose Equivalent) on the Landauer-supplied Calibration Certificate.
3. Click READ to obtain four (4) readings of the nanoDot.
4. Repeat Steps 1-3 for each nanoDot at a given dose level.
5. After all three nanoDots at a given dose level have been read, take care to return them back to their correctly labeled envelope before proceeding to the next dose level.
6. Proceed to the next dose level.
7. Repeat Steps 1-6 for all dose levels in the Calibration Set, including the UNEXPOSED (Zero Dose) nanoDots.
8. Review calibration data and if no anomalies, ACCEPT calibration.

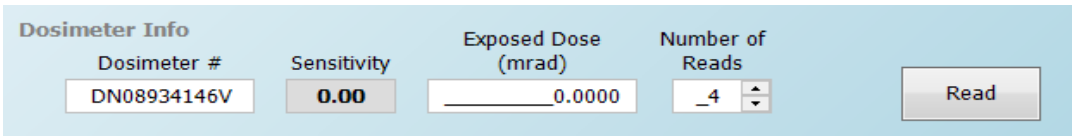
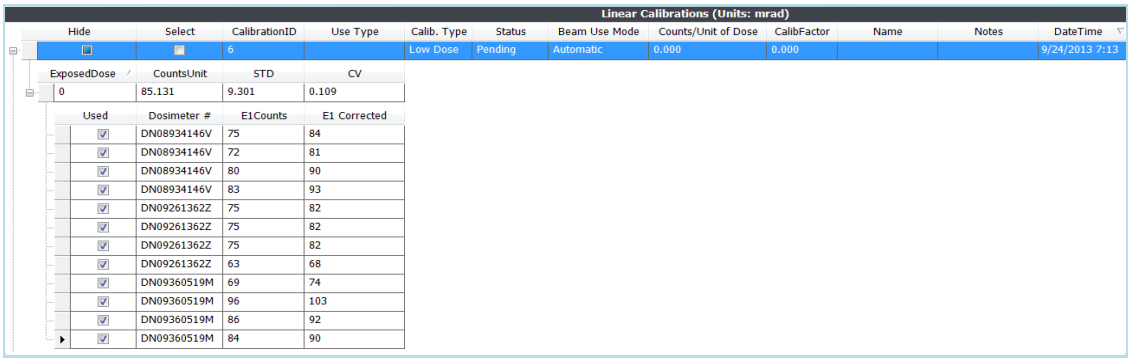


Figure 48: Calibration Screen Dosimeter Info fields

3 MicroSTARii® Reader Tests at Installation (continued)

For each dose level a total of twelve readings (12) will be obtained, four (4) for each of the three (3) nanoDots at a given dose level.

The coefficient of variation for all twelve (12) nanoDot readings at a given dose level (excluding the UNEXPOSED dose level), should be ≤ 0.05.



Linear Calibrations (Units: mrad)

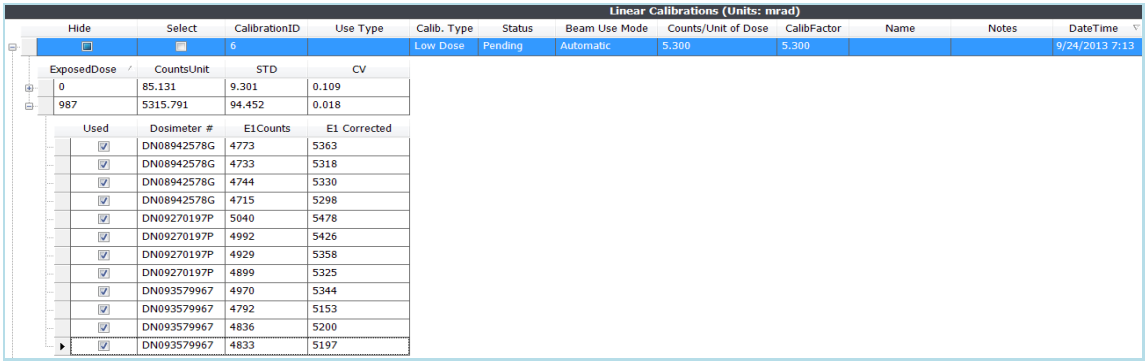
Hide	Select	CalibrationID	Use Type	Calib. Type	Status	Beam Use Mode	Counts/Unit of Dose	CalibFactor	Name	Notes	DateTime
		6		Low Dose	Pending	Automatic	0.000	0.000			9/24/2013 7:13

ExposedDose	CountsUnit	STD	CV
0	85.131	9.301	0.109

Used	Dosimeter #	E1Counts	E1 Corrected
☑	DN08934146V	75	84
☑	DN08934146V	72	81
☑	DN08934146V	80	90
☑	DN08934146V	83	93
☑	DN09261362Z	75	82
☑	DN09261362Z	75	82
☑	DN09261362Z	75	82
☑	DN09261362Z	63	68
☑	DN09360519M	69	74
☑	DN09360519M	96	103
☑	DN09360519M	86	92
☑	DN09360519M	84	90

Figure 49: Calibration Screen detail showing unexposed calibration dosimeter readings

Dose levels other than UNEXPOSED should yield a CV ≤ 0.05. Any OUTLIER readings can be UNSELECTED by unchecking the USED checkbox to remove them from the calibration factor computation.



Linear Calibrations (Units: mrad)

Hide	Select	CalibrationID	Use Type	Calib. Type	Status	Beam Use Mode	Counts/Unit of Dose	CalibFactor	Name	Notes	DateTime
		6		Low Dose	Pending	Automatic	5.300	5.300			9/24/2013 7:13

ExposedDose	CountsUnit	STD	CV
0	85.131	9.301	0.109
987	5315.791	94.452	0.018

Used	Dosimeter #	E1Counts	E1 Corrected
☑	DN08942578G	4773	5363
☑	DN08942578G	4733	5318
☑	DN08942578G	4744	5330
☑	DN08942578G	4715	5298
☑	DN09270197P	5040	5478
☑	DN09270197P	4992	5426
☑	DN09270197P	4929	5358
☑	DN09270197P	4899	5325
☑	DN093579967	4970	5344
☑	DN093579967	4792	5153
☑	DN093579967	4836	5200
☑	DN093579967	4833	5197

Figure 50: Calibration Screen detail – additional dosimeter data showing acceptable CV

Continue to read out all Calibration dosimeters in the dose range being evaluated: low or high dose.

At the end of the calibration, review the data to ensure that all dose levels have a CV ≤ 0.05. If so, click ACCEPT to save the calibration data for the range being evaluated.

3 MicroSTARii® Reader Tests at Installation (continued)

In the popup window that appears, type a NAME for the calibration that is descriptive and select OTHER from the list if a Cs-137 Calibration Set was used and DIAGNOSTIC if an 80 kVp Calibration Set was used.

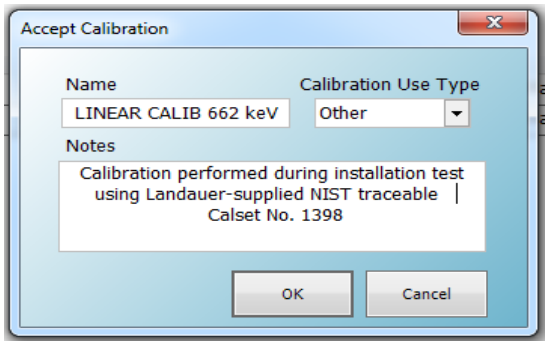


Figure 51: Accept Calibration Pop-Up Window

Click OK to ACCEPT the calibration. The list of available calibrations will then be updated and should include the calibration just completed as shown below.

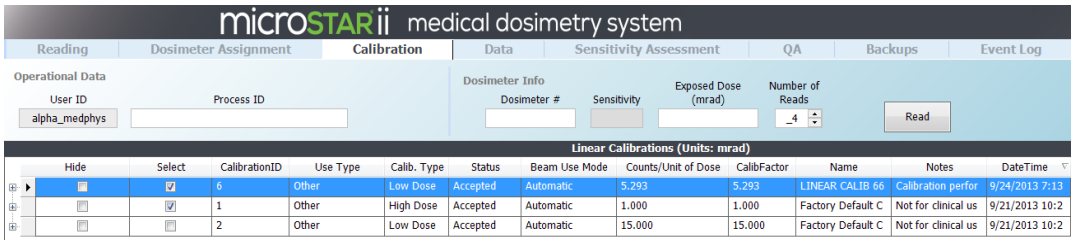


Figure 52: Calibration data list showing factory defaults and new calibration

After completing a calibration for both the low dose and high dose ranges, ensure both are listed and selected and then click SAVE SELECTION at the bottom of the screen.

PART 1E: Post-calibration verification using NIST-traceable QC Set

The next step is to verify the calibration(s) by reading the nanoDot dosimeters in the NIST-traceable QC Set that came with your Calibration Set.

Go to the Configuration Screen and ensure that the options selected correspond to those shown in Figures 53 and 54 and click SAVE.

3 MicroSTARii® Reader Tests at Installation (continued)

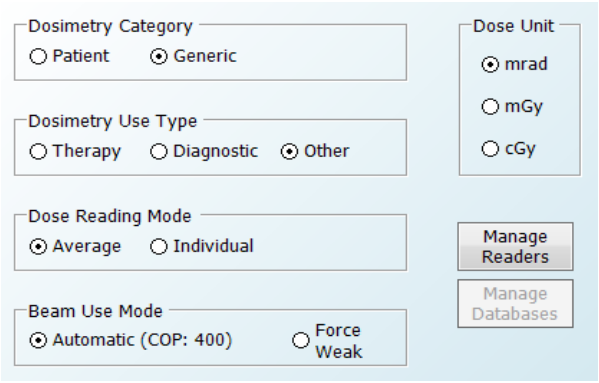


Figure 53: Reading parameters

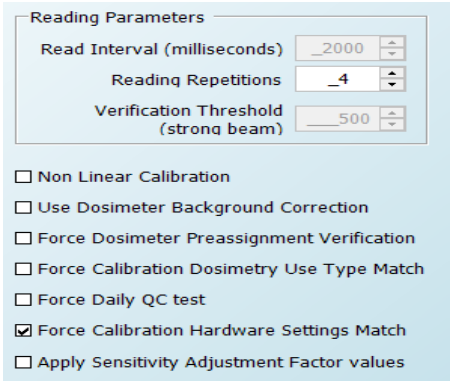


Figure 54: Additional reading parameters

Go to the Reading Screen and enter a Process ID that signifies that data being acquired is part of a Post Calibration verification using QC nanoDots with a known exposed dose, e.g. “Post Cal QC”. Scan the dosimeter serial number and respond YES to the question: Is this a screened nanoDot ?

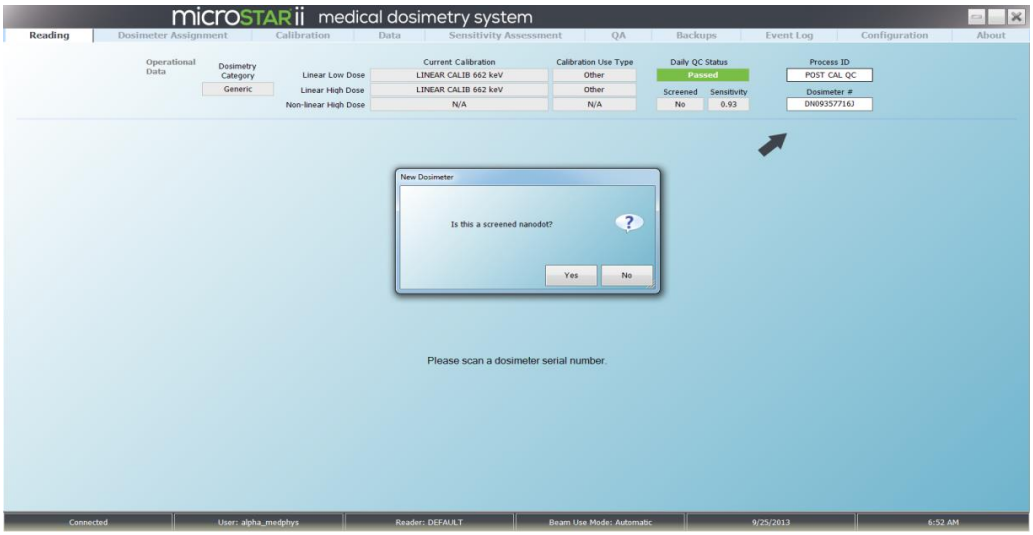


Figure 55: Reading screen settings for Post Calibration Verification using QC nanoDots

Click YES when prompted with the message: Process ID [---] does not exist. Create ?

Insert the nanoDot in the reader drawer and click READ.

The nanoDot will be read four (4) times and the computed dosimetry results will be displayed on screen as shown in Figure 56.

Verify that the computed dose is within 5% of the known exposed dose reported on Landauer certificate and repeat the measurement for all QC nanoDots.

3 MicroSTARii® Reader Tests at Installation (continued)

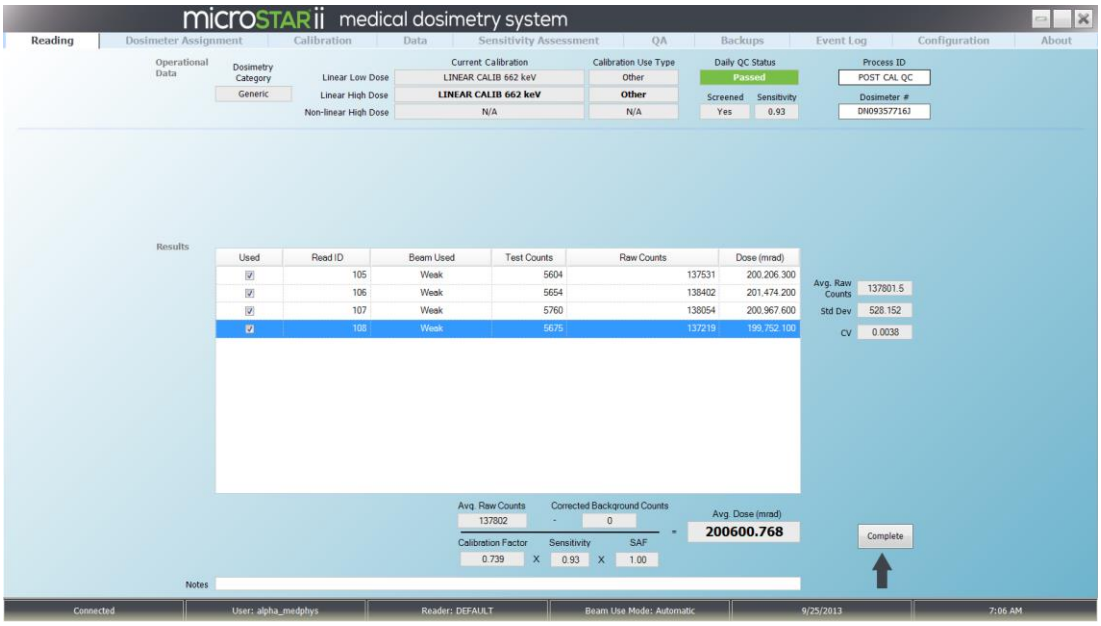


Figure 56: Reading screen results for Post Calibration Verification using QC nanoDots

STEP 2: CALIBRATION FOR CLINICAL MEDICAL DOSIMETRY USE IS BASED ON APPLICATION

Figure 57: An example of a therapy-specific clinical calibration geometry for 6 MV dosimetry: Dosimeters (3-4) are positioned on the beam axis on a sheet of superflab sitting on 10+ cm of solid water. Additional thicknesses of solid water are added to achieve a thickness of d_{max} for depth dose measurements. Alternatively the dosimeters can be exposed on the surface for surface dose measurements. SSD=100 cm in the plane of the dosimeter. Default dose levels for standard linear calibration: 50, 100, and 200 cGy. For applications in which measured doses are expected to exceed 300 cGy, a non-linear calibration employing the following dose levels is recommended: 50, 100, 300, 500, 800, 1000, and 1300 cGy.

IMPORTANT ANNOUNCEMENT

BEFORE COMMENCING MEDICAL DOSIMETRY MEASUREMENTS WITH YOUR READER PLEASE REGISTER FOR A MICROSTARii® QA PROGRAM TRAINING WEBINAR TO GAIN A BETTER UNDERSTANDING OF THE MICROSTARii® MEDICAL DOSIMETRY SYSTEM.

IF YOU DO NOT RECEIVE AN EMAIL ANNOUNCEMENT WITH DETAILS OF THESE SESSIONS, CONTACT CUSTOMER SERVICE.

How to Contact Landauer Technical Support

Contact Information

Address: Landauer Customer Service
2 Science Rd. Glenwood, IL 60425

Telephone: 800-561-2708

Email: inlightcustserv@landauerinc.com

Operating Hours: Monday – Friday: 8:00 am to 4:30 pm Central Time.

When calling Landauer, please provide the representative with the following information:

- Your Contact Information: Name, Phone #, email address, & facility
- How long have you had your system ?
- Are you calling for information or immediate assistance with a system failure ?
- What is the severity of the problem ?
- Is your device operational ?
- Is the problem related to hardware or software ?
- Be prepared to provide the Reader Serial # (see back of reader) and the software version you are currently using (see the About Screen)

Please provide additional specific details of your hardware or software failure:

- Who was operating the system at the time of the problem ?
- What security level does that user have ? (Admin, Advanced Operator or Operator)
- Have you seen this problem before ? If so, how often ?
- Were there any unusual warnings or other symptoms before this problem occurred ?